DISSERTATION
ON

"ASSESS THE EFFECTIVENESS OF PSYCHO EDUCATION MODULE ON KNOWLEDGE REGARDING EXTRA PYRAMIDAL SYMPTOMS AMONG CAREGIVERS OF PATIENTS ON ANTIPSYCHOTIC DRUGS ATTENDING OUTPATIENT DEPARTMENT AT IMH, CHENNAI"

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CERTIFICATE

This is to certify that the dissertation titled **"ASSESS THE EFFECTIVENESS OF PSYCHO EDUCATION MODULE ON KNOWLEDGE REGARDING EXTRA PYRAMIDAL SYMPTOMS AMONG CAREGIVERS OF PATIENTS ON ANTIPSYCHOTIC DRUGS ATTENDING OUTPATIENT DEPARTMENT AT IMH, CHENNAI"** is a bonafide work done by **Mrs. Bellarmin-fernando Prudensia,** M.Sc Nursing II year Student, College of Nursing, Madras Medical College, Chennai-3 submitted to The Tamil Nadu Dr. M.G.R Medical University, Chennai, in partial fulfillment of the requirement for the award of degree of **MASTER OF SCIENCE IN NURSING ,BRANCH-V, MENTAL HEALTH NURSING,** under our guidance and supervision during the academic year 2016 -2018.

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ABSTRACT

Antipsychotic drugs are administered to control the symptoms of psychosis such as hallucinations and bizarre or paranoid behavior. These drugs calm without sedation or reduction in alertness. Acute extra pyramidal symptoms are like acute dystonia, akathisia and parkinsonism develop within hours or weeks after initiating or increasing doses of antipsychotics. **Title: "**Assess the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai**".Objectives:** To assess the pre test and post test level of care givers knowledge regarding extra pyramidal symptoms and find out the effectiveness of psycho education module and association of post test knowledge score with A selected demographic variables .**Methods and materials:** A pre experimental design was chosen. Non probability convenient sampling technique used to select the sample. 60 care givers were the sample. Glasgow Antipsychotic Side-effect Scale (GASS) was used to assess the care givers knowledge level. **Results**: In pre test, care givers knowledge score was 30.15after the administration of psycho education module their knowledge score was 13.63. Difference is 16.51.It was statistically significant at $p<0.001$ level. **Conclusion**: After psycho education module, the caregivers gained good level knowledge score. So Psycho education module has significant impact in gaining of knowledge score among care givers of antipsychotic patients.

Key words: Psycho education module, knowledge, extra pyramidal symptoms, care givers.

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LIST OF ABBREVIATIONS

S.NO	ABBREVIATION	EXPLANATION
1	DF	Degree of Freedom
2	DIMD	Drug Induced Movement Disorders
3	EPI	Early Psychosis Intervention
4	EPS	Extra Pyramidal Symptoms
5	ESRS	Extra Pyramidal Symptom Rating Scale
6	FEP	First Episode Psychosis
7	HOD	Head Of the Department
8	IMH	Institute of Mental Health
9	NMS	Neuroleptic Malignant Syndrome
10	OPD	Out Patient Department
11	RCT	Randomized Controlled Trials
12	SD	Standard Deviation
13	SGA	Second Generation Antipsychotics
14	TD	Tardive Dyskinesia

CHAPTER - I

INTRODUCTION

"Medicines are nothing in themselves, if not properly used, but the very hands of the God, if employed with reason and prudence"

- Herophilus

Psychosis is the most severe psychiatric disorder, in which there is marked impairment of behavior, serious inability to think coherently, comprehend and lack of insight. Positive symptoms include hallucinations, delusions and experiences that are not characteristic of normal mental life. Negative symptoms represent deficits in normal functions such as blunted affect, a social behavior and diminished motivation. Symptoms of impaired cognition include deficits in working memory, processing speed and social norms[1].

The mesolimbic pathway being associated with the positive symptoms and mesocortical pathway associated with negative and cognitive symptoms[2]. Dopamine role in the causation of psychosis is complex. The positive symptoms are due to over activity in the mesolimbic dopaminergic pathway activating D2 receptors whereas negative symptoms may result from decreased activity in the mesocortical dopaminergic pathway where D1 receptors dominate[3].

An antipsychotic drugs are administered to control the symptoms of psychosis such as hallucinations and bizarre or paranoid behaviour. These drugs calm without sedation or reduction in alertness[4].

In the early 1950s, a few obscure chemicals tested in the back wards of mental hospitals ushered in the modern era of psychotropic drug treatments for mental disorders. Today, medication with antipsychotic drugs has become the

principal form of treatment used in mental hospitals, nursing homes, institutions for the retarded, and board and care homes that house the mentally ill. After the antipsychotics came lithium, the antidepressants, and the minor tranquilizers. Each year more than one-fifth of non institutionalized adults receive prescriptions for psychotropic drugs[5].

The first antipsychotic chlorpromazine was introduced in 1952[6]. They act through D2 receptor blockade. These typical antipsychotics chlorpromazine, haloperidol or fluphenazine are effective in relieving positive symptom of the psychosis but have some serious limitations such as lack of efficacy against negative symptoms and adverse effects like extra pyramidal symptoms[7]. The inhibitory effects of dopaminergic neurons are normally balanced by the excitatory actions of cholinergic neurons in the striatum. Blocking dopamine receptors alters this balance, causing a relative excess of cholinergic influence, which results in extra pyramidal motor effects. The appearance of the movement disorders is generally time and dose dependent[8]. Advances in the treatment have emerged from discovery of newer antipsychotics also called as second generation antipsychotics potentially antagonize the 5HT2 receptor, block the D2 receptor less potently than typical antipsychotics. The development of these atypical antipsychotics such as Clozapine, Risperidone, Olanzapine, Quetipine in 1990's fulfilled great expectations in treatment of psychosis by reducing the extra pyramidal symptoms [9].

Antipsychotics induced extra pyramidal symptoms include a variety of movement disorders Acute extra pyramidal symptoms are like acute dystonia, akathisia and parkinsonism develop within hours or weeks after initiating or increasing doses of antipsychotics. Tardive dyskinesia and tardive dystonia are delayed onset syndromes and usually develop after a prolonged use of antipsychotics[10]. The term "neuroleptic" meaning "to fix or hold a neuron" was used to describe the neurological adverse effect of conventional antipsychotics rather than their therapeutic effects[11].

Caring for someone with a mental disorders can affects the dynamics of family. It takes up most of the carers time and energy. The family responsibility is providing care for people with mental disorders has increased in past three decades. This has been mainly due to trend towards community care and de-hospitalization of psychiatry patients [12].

Relatives are usually involved in caring for the patients who are receiving antipsychotic drugs. Thus it is essential that all caregivers understand the medication, side effects, precautions and the caregiver's role. Investigators have proved that educating caregivers on the importance of compliance to antipsychotic drugs, side effects and their role in caring for mentally ill patients can reduce relapse[13]. Caregiver's stress, burden and sense of being overwhelmed by the care giving roles have been linked to patient's persistent behavioural problems and caregiver's perceived or actual inability to handle them. So their role is important in caring for their mentally ill relatives[14].

1.1 NEED FOR STUDY:

In India the reported rate of mental illness is 100 per thousand population .It has been estimated that 20% - 50% of any patient population is at least partially complaint and that in patients with schizophrenia and related psychotic disorders rates run as high as 70%-80%. The WHO is currently undertaking a global survey of 26 countries in all regions of the world , based on ICD and DSM criteria. The first published figures on the 14 country surveys completed to date, indicate that, of those disorders assessed, anxiety disorders are the most common in all but 1 country (prevalence in the prior 12 - month period of 2.4% to 18.2%) and mood disorders next most common in all but 2 countries (12-month prevalence of 0.8% to 9.6%), while substance disorders (0.1%–6.4%) and impulse-control disorders (0.0%–6.8%) were consistently less prevalent. It has been estimated that of largest prevalence rate of

psychiatric illness . In the U.S find the anxiety disorders affect 15.7 million people in united states each year[15].

The United States, Colombia, the Netherlands and Ukraine tended to have higher prevalence estimates across most classes of disorder, while Nigeria, Shanghaisi and Italy were consistently low , and prevalence was lower in Asian countries in general. Cases of disorder were rated as mild (prevalence of 1.8%–9.7%), moderate (prevalence of 0.5%–9.4%) and serious (prevalence of 0.4%–7.7%) .However, these are widely believed to be underestimates, due to poor diagnosis (especially in countries without affordable access to mental health services) and low reporting rates, in part because of the predominant use of self-report data, rather than semi-structured instruments such as the Structured Clinical Interview for DSM-IV (SCID); actual lifetime prevalence rates for mental disorders are estimated to be between 65% and 85%[16].

The incidence of psychotic disorders across 17 areas in six countries -- the UK, France, Italy, the Netherlands, Spain and Brazil -- using comparable methodology. Their data was drawn from people aged 18-64 who contacted mental health services after a suspected first psychotic episode, which included 2,774 incident cases in total. They found the overall incidence of psychotic disorders to be 21.4 per 100,000 person-years, but discovered wide variations between different areas, from a low of 6.0 per 100,000 person-years in the rural area around Santiago (Spain), to a high of over 45 in inner-city Paris and Southeast London. This variation could not be explained by differences in the age, sex and ethnic composition of the population across these areas[17]

A study revealed that the extra pyramidal symptoms were more commonly seen in males (62.85%), the age of incidence of maximum in the age group of 34.28, Maximum was seen among the patients on the Risperidone (45.7%), Involvement of the extremities was common (42.85%) and 64.28% of

individuals had moderate severity and 54.28% of individuals were aware of the extra pyramidal symptoms which provided mild distress[18].

As a part of the pharmaco vigilance programme of India, the authors have assessed 10 physician-reported cases of EPS among the 1,830 patients who were prescribed risperidone within the time period of January 2012-December 2014 in a tertiary care hospital in South India. Causality, severity, and preventability assessments of adverse reaction were done as per Naranjo's, Hartwig's, and Thornton's scale respectively. 10 cases, a dose-dependent occurrence of EPS was noted in all and the time duration for development of EPS ranged from 1 week to 2 years. Four patients developed EPS at a dose of 6–8 mg, 4 developed at a dose of 4–6 mg, and the remaining 2 developed at 2 and 1 mg[19]

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Due to short hospital stay and the involvement of the family in the care of the patient, the contact of the patient with healthcare personnel is minimal. It is the family which stays with the patients for 24 hours of the day helping the patient meet his/her needs. So it is very important that caregivers receive sufficient knowledge as to how to care for their relatives who are on antipsychotic drugs. [21]

1.2 STATEMENT OF THE PROBLEM:

"Assess the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai**"**

1.3 OBJECTIVES OF THE STUDY:

1. To assess the socio demographic variables and pre test knowledge of care giver regarding extra pyramidal symptoms..
2. To determine the pre test and post test knowledge of care giver regarding extra pyramidal symptoms.
3. To find association between post test knowledge score and selected demographic variables.

1.4 OPERATIONAL DEFINITIONS:

1) **Assess**: It is refers to the statistical analysis of knowledge through MGASS among care givers.
2) **Effectiveness**: Effectiveness is the extent to which an activity fulfils its intended purpose or function.
3) **Psycho education module:** It is defined as well planned and arranged programme through which knowledge is provided to subjects and improvement is based on outcome.
4) **Knowledge**: It is defined as an expertise, and skills acquired by a person through experience or education; the theoretical or practical understanding of a subject.
5) **Extra pyramidal symptoms**: Extra pyramidal symptoms (EPS) are various movement disorders such as acute dystonic reactions, pseudo parkinsonism or akathisia suffered as a result of taking dopamine antagonists, usually antipsychotic (neuropleptic) drugs, which are often used to control psychosis.
6) **Caregivers**: It refers to the people who are taking care of patients receiving antipsychotic drugs

7) **Antipsychotics:**Drugs which is used to treat the psychotic symptoms and also produce EPS**.**

8) **Psychiatric hospital**: It refers to Institute of Mental Health l where the psychiatric patients are attending OPD

1.5 ASSUMPTION:

The proposed study assumes that:

Care givers doesn't have enough knowledge regarding extra pyramidal symptoms, after psycho education module the care givers will gain more knowledge regarding extra pyramidal symptoms

1.6 HYPOTHESIS:

H1: The mean post test knowledge score of caregivers undergoing the structured teaching programme is more than the mean pre-test score.

H2: There will be a significant association between pre-test scores of caregivers and with selected demographic variables.

1.7 DELIMITATIONS OF THE STUDY:

- The study is limited to the caregivers of patients receiving antipsychotics attending the OPD at IMH, Chennai.
- The period of study is limited to 4 weeks.

CHAPTER -II

2.1. REVIEW OF LITERATURE

The review of literature is defined as a broad comprehensive, in depth systematic and critical review of scholarly publications, unpublished scholarly print materials, audio visual materials and personal communication. Literature having a direct bearing on the present subject was reviewed in order to have an insight into the selected problem area and build the foundation of the study thus becoming familiar with the related article, studies, techniques, tools used and problems encountered by previous researchers. These helped in planning the framework design, developing tool and designing the interview schedule.

The review of literature for the present study has been organised under the following headings:-

The studies under review are organised under three headings.

2.1.1 Literature review related to knowledge of family members on care of patients receiving antipsychotic therapy.

2.1.2 Literature review related to the side effects of antipsychotic therapy.

2.1.3 Literature review related to EPS by antipsychotic drugs.

2.1.1. Literature Review related to knowledge of family members on care of patients receiving antipsychotic therapy

Vimala D R(2016) conducted descriptive study was to assess the knowledge ,attitude and practice of family members of client with mental illness among Medicaid patient with schizophrenia, at community setting of California. A size sample of 100 family members was selected with purposive sampling technique. Data was collected with structured questionnaires with four modules. The study result shows that

78% were able to identify a cause or precipitating the onset of illness ,97% of that mental illness is curable with medication .80% of them allowed the mentally ill client to attend the social gathering or visit places '25% 0f the participants objected to marrying family member of a mentally ill person. The mean score was statistically higher among those with secondary level of education(M= 16.6,SD= 4.9) in comparison with those with primary level of education (M= 13.9,SD= 4.50) .family members of urban area scored significantly higher(M= 17.2,SD= 4.5)than those from rural area (m= 14.3,sd= 4.8)[22]

Mao –Sheng Ran ,Meng – Zea Xang, Cecilia Lai – wan,Julian Leff, et al (2016) conducted descriptive study was to explore the characteristics and efficacy of psycho educational family intervention for persons of schizophrenia in rural community settings, China .A sample size of 326 were selected by cluster randomised sampling technique . The tool of this study involved drug treatment and psycho educational family intervention. The study results show that a gain in knowledge , a change in relatives caring attitude towards the patients and increase in psycho educational family group (P< 0.05,0.001) most important relapse rate over 9 months in this group. (16.3%) was half of that drug group only (37.8%) and just over one quarter of that control group (61.5%)(p<0.05) moreover there were also no significant differences of demographics for the main carers[23].

Sailesh P. (2015) conducted descriptive study was to assess the impact of non adherence and other factors associated with resources and cost incurred by people with schizophrenia. 658 samples were studied and it patients in other types of institution. Cross-sectional survey method was used and data was collected with the help of a structured interview schedule. The study was conducted to assess the impact of non adherence and other factors associated with resource use and costs incurred by people The study results shows that the rate of reported non-adherence was lower in the sub sample of patients resident in hospital (11.2%) compared with (21.2%) [24].

Wyatt RG (2017) conducted study was to examine **Pope A, Adams C, Paton C, Weaver T. (2016)** conducted an exploratory descriptive study design was utilized, whereby a sample of nursing staff was given a questionnaire developed to determine knowledge about antipsychotic drugs and their use with the older persons. Questionnaires were distributed to 100 nursing staff, including registered general nurses, registered mental nurses, nursing assistants and care assistants. Of the 100 questionnaires distributed, 62 were returned and 57 were completely substantially enough for data analysis. Results indicated that the use of antipsychotic drugs within the psychiatric hospital setting was substantial, with 43.7% of patients receiving antipsychotic drugs, for an average length of time of 1.8 years. It was concluded that nursing staff participants from all three work settings revealed a number of significant knowledge gaps, particularly with regard to appropriate indications for antipsychotic drugs with older persons and the side effects of antipsychotic drugs[25].

2.1.2 Literature Review related to side effects of antipsychotic therapy

relationships between dopamine D (2) receptor binding in both substantia nigra and temporal cortex with extra pyramidal symptoms among antipsychotic-treated patients with schizophrenia. Previous studies have highlighted a central role for nigral dopamine D (2) receptors in the control of motor functions. Single-photon emission-computed tomography was used to determine dopamine D (2/3) apparent binding potential in 13 antipsychotic-treated (seven with clozapine, four with olanzapine and two with haloperidol) patients with schizophrenia. Extra pyramidal symptoms were assessed with the Simpson and Angus Scale (SAS). Result was found that statistically significant correlation was observed between dopamine D(2/3) receptor apparent binding potential in the substantia nigra and extra pyramidal side-effects. Conclusion supports the role of dopamine D (2) auto receptors in substantia nigra regarding drug-induced movement disorders[26].

Miller CH, Mohr F, Umbricht D, et al (2017) conducted study was to provide information on patient-reported side effects from a cross-section of real-world patients. Specifically, data on side effects were tabulated for patients taking at least one of the following atypical antipsychotic medications: Aripiprazole, Olanzapine, Paliperidone, Quetiapine, Risperidone, or Ziprasidone. Approximately 54 percent of the 353 respondents reported having experienced a side effect as a result of taking an atypical antipsychotic medication. Most common side effects mentioned included the following: weight gain/hunger, tiredness/lethargy, and lack of coordination/muscle problems, such as tenderness twitches, and tremors. The result was 172 patients who listed at least one side effect, 30 to 35 percent of patients reported weight gain always hungry and/or tiredness/lethargy. Lack of coordination and muscle problems, such as twitches, tenderness, or tremors, were mentioned by 5 to 10 percent of patients. It was concluded that antipsychotic-related side effects continue to be highly prevalent among atypical antipsychotic exposed patients[27].

Raja. M (2017) conducted study was to develop an evidence base for recommendations on the use of atypical antipsychotic for patients with schizophrenia where 12 649 patients in 52 randomized trials comparing atypical antipsychotic with The results of Meta-regression suggested that dose of conventional antipsychotic explained the heterogeneity. It was concluded that there is no clear evidence that atypical antipsychotic are more effective and better tolerated than conventional antipsychotics. Conventional antipsychotics should usually be used in the initial treatment of an episode of schizophrenia unless the patient has previously not responded to these drugs or has unacceptable extra pyramidal side effects[28].

Anirudh G (2017) conducted descriptive study was to investigate the effectiveness of training and structured assessment on clinical and social outcome of patient receiving maintains medication of depot antipsychotics among nurses working in south Gujarat, India. A sample of

forty nine nurses was selected with simple random technique. Data was collected with help of structured questionnaires. Results shows that 40% of majority of practice nurses received scant referral information and worked without protocols. There was a unexpected increase awareness of problem of severely mentally ill.[29]

Tuppurainen H, Kuikka JT, Viinamaki H, Husso M, Tiihonen J. (2016) conducted study was in Canada, Ontario to compare the incidence of admissions to hospital for stroke among older adults with dementia receiving atypical or typical antipsychotics. As a sample, 32,710 older adults (< 65 years) with dementia (17845 dispensed an atypical antipsychotic and 14865 dispensed a typical antipsychotic) were selected. The results indicated that after adjustment for potential confounders, participants receiving atypical antipsychotics showed no significant increase in risk of ischemic stroke compared with those receiving typical antipsychotics. This finding was consistent in a series of subgroup analysis, including ones of individual atypical antipsychotic drugs and selected subpopulations of the main cohorts. It was concluded that older adults with dementia who take atypical antipsychotics have a similar risk of ischemic stroke to those taking atypical antipsychotics[30]

Kennedy , Mion (2016) conducted descriptive study was to evaluate knowledge of antipsychotic drugs use with psychiatric patients among nurses in selected nursing home in US, A sample size of 90 nurses is selected with randomised sampling technique . Data was collected with the help of structured questionnaires. The result shows that only 27% of nursing staff responding in a satisfactory way. [31.]

Pierre JM. (2016) conducted study on atypical antipsychotic are indicated for the treatment of refractory schizophrenia, and in some cases, bipolar disorders; they are also used off-label for symptoms such as agitation, anxiety, psychotic episodes, and obsessive behaviors, as well as in children and the elderly. The findings was done on a recent meta-analysis of 150 double-

blind, randomized controlled trials (N = 21,533) raised questions about the notion that atypical antipsychotic as a class are truly superior to typical antipsychotic in terms of efficacy and side-effects. It was concluded that he older agents have been associated with adverse effects such as extra pyramidal symptoms, severe movement disorders, and sudden cardiac death, among others[32].

Levenson. A (2016) conducted exploratory study was among nurses knowledge of antipsychotic drug use with older persons within the three units of the psychiatric hospital were collected directly from patient medical and nursing case notes, from which the nurses recorded their data on care plans regarding the patient' s progress. Data analysis procedures Simple descriptive statistics were calculated for demographic variables and the questionnaire responses. The three units of the psychiatric hospital had 265 patients, and 43.7% (n=114) were receiving antipsychotic medications at the time of the study . The reasons given for the use of antipsychotic medications included the following: agitation/restlessness (62.8%, n=72) severe anxiety (41.3%, n=48) behavioral problems (18.9%, n=22) psychosis (13.7%, n=16) depression (8.6%, n=10) cognitive impairment (6.0%, n=7) insomnia (3.4%, n=4) alcohol misuse (1.7%, n=2) self-neglect (0.8%, n=1). The average length of time that the hospital patients had been receiving antipsychotics was 22.0 months, with a range of one month to 108 months. Interestingly, almost 36% (n=41) of the hospital patients receiving antipsychotics had documentation in the case notes of conditions that might be indicative of side-effects due to antipsychotic drug use . Ability to correctly identify antipsychotic drugs, a majority of nursing staff could correctly identify antipsychotic drugs by name, with a range from 60.9% (trifluoperazine) to 75.0% (promazine). A surprising number of nursing staff also indicated that they 'didn't know' whether an actual antipsychotic drug was in fact

an antipsychotic, with a range from 25.0% (promazine) to 34.1% (trifluoperazine)[33].

William Honer G, (2015) study was taken to identify the safety and tolerability of antipsychotic in recent clinical studies. A survey was conducted of all 167 eligible studies published between 2002 and 2007 on the Cochrane Schizophrenia Group register and the result was extra pyramidal side-effects (EPS) and weight gain were most frequently assessed. A minority of reports addressed metabolic abnormalities, aversive subjective experiences and sexual dysfunction. Published rating scales were frequently used to evaluate EPS, but systematic methods were rarely applied to other treatment-emergent problems. The definition of individual adverse effects and the manner of reporting were inconsistent. It was concluded that the way in which safety and tolerability data are collected and reported in clinical studies does not allow for fair and meaningful comparison of the relative risk profiles of individual antipsychotic drugs[34]

Lili Kopala C (2014) study was conducted on the important role of the mental health nurse in facilitating adherence has been acknowledged, however, there has been little exploration of how nurses themselves perceive this aspect of their role. A qualitative study was conducted to explore the perceptions of mental health nurses employed in inpatient settings regarding their role in facilitating medication adherence. Focus groups conducted with 22 nurses from three inpatient settings in metropolitan Melbourne[35]

Cuningham Owens DG (2014) conducted study indicated that young males have an increased susceptibility to develop extra pyramidal side effects, although the effects can and do occur in both sexes. The reasons for increased risk in males are not fully known but may be related to increased muscle mass in men. The incidence of extra pyramidal side effects also appears to be dose dependent. In addition, intramuscular dosing of neuroleptics may increase the chances of causing extra pyramidal side effects study stated that the traditional

anti-psychotic agents block receptors for dopamine in the CNS, and they all can cause serious movement disorders referred to as extra pyramidal reactions. Nurse is often involved in the routine screening and monitoring clients for the presence of extra- pyramidal side effects[36].

Wyatt RG(2014) conducted study was conducted on the treatment of schizophrenia which changed drastically with the discovery of antipsychotic medications in the 1950s, the release of clozapine in the US in 1989 and the subsequent development of the atypical or novel antipsychotic. EPS thought to have a significant impact on subjective tolerability and adherence with antipsychotic therapy in addition to impacting function. Unlike conventional antipsychotic medications, atypical antipsychotic have a significantly diminished risk of inducing acute EPS at recommended dose ranges. This paper reviews the available evidence regarding the incidence of acute EPS and Tardive syndromes with atypical antipsychotic therapy. Estimates of incidence are subject to several confounds, including differing methods for detection and diagnosis of EPS, pre treatment effects and issues surrounding the administration of antipsychotic medications. Results showed the use of atypical antipsychotic as first line therapy for the treatment of schizophrenia is based largely on their reduced risk of EPS compared with conventional antipsychotic. It was concluded that the EPS advantages offered by the atypical antipsychotic must be balanced against other important adverse effects, such as weight gain and diabetes mellitus, now known to be associated with these drugs[37].

Miller CH, Mohr F, Umbricht D (2014) conducted study to assess the faced with these numerous potential side effects, many patients on traditional antipsychotic drugs find it difficult to tolerate their medication and they stop taking it. Patients who are helped by antipsychotic drugs cannot be persuaded to continue taking the drugs when they are feeling well. The American Psychiatric Association estimates that 50% of schizophrenic patients stop taking their medication within six months of discharge because of troublesome side effects such as muscle spasms, restlessness and tremors. Statistics gathered

at Oregon Health Sciences University show that 52% of schizophrenic patients are readmitted within a year of hospital discharge, and this figure applies only to patients with no previous history of readmission. Statistics worsen with each cycle of discharge and readmission. One study placed the relapse rate for schizophrenic patients who were noncompliant with medication at76% within one year[38].

Sink KM, Holden KF, Yaffe K. (2016) conducted a study was done on the behavioral and psychological symptoms of dementia (BPSD) and the effectiveness of antipsychotic drugs which are prescribed mostly. A qualitative review of the data was done on the efficacy and safety of antipsychotic drugs for BPSD and examined for safety issues with an especial focus on recent research. Results were found that typical and atypical antipsychotic drugs both attenuate the severity of BPSD; both categories of drugs increase the risk of cerebrovascular and other adverse events, as well as the risk of death. The risk appears greater with the typical drugs, with higher doses, and during the initial weeks of treatment. Both drug- and patient-related factors appeared to mediate this increase in risk. It was concluded that antipsychotic drugs should be considered for BPSD only if there is a specific need, decision-making should be individualized and documented after a risk-benefit analysis and verified for extra pyramidal symptoms[39].

John Kamin, M.D., Sumita Manwani, M.D. and Douglas Hughes, M.D(2016) investigated a study was conducted on the movement disorders in first-episode psychosis are increasingly recognized and compared antipsychotic exposed (< 12 weeks) with non exposed first-episode patients, and report prevalence as well as clinical and demographic variables associated with extra pyramidal dysfunction. Data are baseline assessments from a multicentre, international drug trial of first-episode psychosis (n = 535). Analysis included the extra pyramidal Symptom Rating Scale, Premorbid Adjustment Scale, and the Positive and Negative Syndrome Scale. Of non-exposed patients, 28.1% (n = 47/167) had at least one mild sign of extra pyramidal dysfunction, as did

46.3% (*n* = 169/365) of previously exposed patients. Hypo kinetic Parkinsonism was the most prevalent disorder. The severity of movement disorders and negative symptoms were correlated and antipsychotic exposure was associated with extra pyramidal signs, the results indicate that many first-episode patients with no exposure to antipsychotic also had extra pyramidal dysfunction[40].

Plesnicar BK (2016) revealed a study was conducted to examine relationships between dopamine D (2) receptor binding in both substantia nigra and temporal cortex with extra pyramidal symptoms among antipsychotic-treated patients with schizophrenia. Previous studies have highlighted a central role for nigral dopamine D (2) receptors in the control of motor functions. Single-photon emission-computed tomography was used to determine dopamine D (2/3) apparent binding potential in 13 antipsychotic-treated (seven with clozapine, four with olanzapine and two with haloperidol) patients with schizophrenia. Extra pyramidal symptoms were assessed with the Simpson and Angus Scale (SAS). Result was found that statistically significant correlation was observed between dopamine D(2/3) receptor apparent binding potential in the substantia nigra and extra pyramidal side-effects. Conclusion supports the role of dopamine D (2) auto receptors in substantia nigra regarding drug-induced movement disorders[41].

Caccia S, Pasina L, Nobili(2015) conducted a study was to provide information on patient-reported side effects from a cross-section of real-world patients. Specifically, data on side effects were tabulated for patients taking at least one of the following atypical antipsychotic medications: aripiprazole, olanzapine, paliperidone, quetiapine, risperidone, or ziprasidone. Approximately 54 percent of the 353 respondents reported having experienced a side effect as a result of taking an atypical antipsychotic medication. Most common side effects mentioned included the following: weight gain/hunger, tiredness/lethargy, and lack of coordination/muscle problems, such as tenderness twitches, and tremors. The result was 172 patients who listed at

least one side effect, 30 to 35 percent of patients reported weight gain always hungry and/or tiredness/lethargy. Lack of coordination and muscle problems, such as twitches, tenderness, or tremors, were mentioned by 5 to 10 percent of patients. It was concluded that antipsychotic-related side effects continue to be highly prevalent among atypical antipsychotic exposed patients[42].

Seidal S, Aigner M, Ossage(2015) conducted a study was to develop an evidence base for recommendations on the use of atypical antipsychotic for patients with schizophrenia where 12 649 patients in 52 randomized trials comparing atypical antipsychotic with The results of Meta-regression suggested that dose of conventional antipsychotic explained the heterogeneity. It was concluded that there is no clear evidence that atypical antipsychotic are more effective and better tolerated than conventional antipsychotics. Conventional antipsychotics should usually be used in the initial treatment of an episode of schizophrenia unless the patient has previously not responded to these drugs or has unacceptable extra pyramidal side effects[43].

Lepping P, (2015) investigated study was done in Canada, Ontario to compare the incidence of admissions to hospital for stroke among older adults with dementia receiving atypical or typical antipsychotics. As a sample, 32,710 older adults (<65 years) with dementia (17845 dispensed an atypical antipsychotic and 14865 dispensed a typical antipsychotic) were selected. The results indicated that after adjustment for potential confounders, participants receiving atypical antipsychotics showed no significant increase in risk of ischemic stroke compared with those receiving typical antipsychotics. This finding was consistent in a series of subgroup analysis, including ones of individual atypical antipsychotic drugs and selected subpopulations of the main cohorts. It was concluded that older adults with dementia who take atypical antipsychotics have a similar risk of ischemic stroke[44].

2.1.3 Literature review related to EPS by antipsychotic drugs.

Sink KM, Holden KF, Yaffe K (2017) conducted study was on extra pyramidal side effects such as dystonias, parkinsonism, and akathisia. Dystonias are prolonged and unintentional muscular contractions of voluntary or involuntary muscles. Neuroleptic-induced Parkinsonism is characterized by the triad of tremor, rigidity, and bradykinesia; Akathisia is characterized by a patient's subjective sense of restlessness, along with such objective evidence of restlessness as pacing or rocking. Extra pyramidal side effects were done on random sampling of about 100 patients receiving antipsychotics. 40% of them reported with dystonia and manifested, albeit laryngeal dystonia or dystonias of other musculature related to breathing. 30% manifested with severe muscular rigidity, fever, an altered level of consciousness, and autonomic instability characterize neuroleptic malignant syndrome. 20% of them reportedwith akathesia and 10% with Tardive dyskinesia[45].

John Kamin, M.D., Sumita Manwani, M.D. and Douglas Hughes (2017) investigated study was taken to identify the safety and tolerability of antipsychotic in recent clinical studies. A survey was conducted of all 167 eligible studies published between 2002 and 2007 on the Cochrane Schizophrenia Group register and the result was extra pyramidal side-effects (EPS) and weight gain were most frequently assessed. A minority of reports addressed metabolic abnormalities, aversive subjective experiences and sexual dysfunction. Published rating scales were frequently used to evaluate EPS, but systematic methods were rarely applied to other treatment-emergent problems. The definition of individual adverse effects and the manner of reporting were inconsistent. It was concluded that the way in which safety and tolerability data are collected and reported in clinical studies does not allow for fair and meaningful comparison of the relative risk profiles of individual antipsychotic drugs[46].

Plesnicar BK, (2016) study indicated that young males have an increased susceptibility to develop extra pyramidal side effects, although the effects can and do occur in both sexes. The reasons for increased risk in males are not fully known but may be related to increased muscle mass in men. The incidence of extra pyramidal side effects also appears to be dose dependent. In addition, intramuscular dosing of neuroleptics may increase the chances of causing extra pyramidal side effects study stated that the traditional anti-psychotic agents block receptors for dopamine in the CNS, and they all can cause serious movement disorders referred to as extra pyramidal reactions. Nurse is often involved in the routine screening and monitoring clients for the presence of extra- pyramidal side effects[47].

Caccia S, Pasina L, Nobili A. (2016) study was conducted on the treatment of schizophrenia which changed drastically with the discovery of antipsychotic medications in the 1950s, the release of clozapine in the US in 1989 and the subsequent development of the atypical or novel antipsychotic. EPS thought to have a significant impact on subjective tolerability and adherence with antipsychotic therapy in addition to impacting function. Unlike conventional antipsychotic medications, atypical antipsychotic have a ignificantly diminished risk of inducing acute EPS at recommended dose ranges. This paper reviews the available evidence regarding the incidence of acute EPS and tardive syndromes with atypical antipsychotic therapy. Estimates of incidence are subject to several confounds, including differing methods for detection and diagnosis of EPS, pretreatment effects and issues surrounding the administration of antipsychotic medications. Results showed the use of atypical antipsychotic as first line therapy for the treatment of schizophrenia is based largely on their reduced risk of EPS compared with conventional antipsychotic. It was concluded that the EPS advantages offered by the atypical antipsychotic must be balanced against other important adverse effects, such as weight gain and diabetes mellitus, now known to be associated with these drugs[48].

Clive Adams, E (2016) conducted a comparative study was done on the prevalence and severity of extra pyramidal side effects (EPSs) in 106 patients treated with Clozapine, 23 patients treated with Risperidone, and 42 patients treated with conventional antipsychotics for at least 3 months. Authors examined differences between the 3 groups with regard to Akathisia and extra pyramidal motor side effects. The results were pointed as prevalence of Akathisia was 7.3% in the Clozapine group, 13% in the Risperidone group, and 3.8% in the group treated with conventional antipsychotics[49].

Charles R. (2016) conducted a cross-sectional descriptive study conducted at Katsina State Psychiatric Hospital. A total of 129 caregivers who presented consecutively. This was developed to assess caregiver burden in relatives of patients with chronic mental illnesses. The factors include the caregiver's health, psychological wellbeing, finances, social life, stigma details, and relations. The instrument has been used to assess caregiver burden not only in dementia but also in schizophrenia. Results were found that a high level of caregiver burden was found in 61 (47.3%) respondents. A higher level of caregiver burden was significantly associated with place of residence and family size. Large proportions of respondents were experiencing a high level of burden; this was significantly associated with family size and place of residence[50].

Martyn-Yellowe IS. (2016) revealed a study on the prevalence of usage of antipsychotic drugs in the USA was reported at 13.9% among individuals aged 40 years and older. Global estimates for 2001 showed that, worldwide, approximately 10 million people suffered from dementia; 8 million are with Parkinsonism 6 million suffering with Alzheimer's disease and overall 24.3 million people are suffering with neuropsychiatry disorders and 60.1% of all people with dementia lived in developing countries. In India, the prevalence of usage of antipsychotic drugs lies in the range of 1.8 to 3.6% among individuals aged 60 to 65 years[51].

Kuipers L. (2015) investigated a study was done on prevalence of acute extra pyramidal signs and symptoms in patients treated with clozapine, risperidone, and conventional antipsychotics. The point-prevalence of rigidity and cogwheeling (EPSs) respectively was 4.9% and 2.4% in the clozapine group, 17.4% and 17.4% in the risperidone group, and 35.7% and 26.2% in the group treated with conventional antipsychotics. Results indicate that risperidone is superior to conventional neuroleptics in that it causes fewer EPSs. In comparison to clozapine, risperidone produced EPS levels that are intermediate between clozapine and conventional antipsychotic drugs[52].

Greenberg JS, Greenly JR, McKean D, Brown R, Griffin-Francell C. (2015) conducted study on nursing personnel research has documented the widespread use of antipsychotic drugs by nursing staff with older persons, although less is known about the knowledge that nurses actually have about these drugs. An exploratory descriptive study design was utilized, whereby a sample of nursing staff was given a questionnaire developed to determine knowledge about antipsychotic drugs and their use with the older persons. Questionnaires were distributed to 100 nursing staff, including registered general nurses, registered mental nurses, nursing assistants and care assistants. Of the 100 questionnaires distributed, 62 were returned and 57 were completely substantially enough for data analysis. Results indicated that the use of antipsychotic drugs within the psychiatric hospital setting was substantial, with 43.7% of patients receiving antipsychotic drugs, for an average length of time of 1.8 years. It was concluded that nursing staff participants from all three work settings revealed a number of significant knowledge gaps, particularly with regard to appropriate indications for antipsychotic drugs with older persons and the side effects of antipsychotic drugs[53].

Tsang HWH, Tam PKC, Chen F, Chang M. (2015) conducted comparative study was done to measure caregiver attitudes to antipsychotic drugs and their adverse side effects and comparing these with the attitudes of the general population. Analysis and comparison of two representative samples

were taken, one comprising 100 caregivers and the other 791 individuals randomly selected from the general population. The setting was on the German speaking cantons of Switzerland. Results showed significantly more positive attitudes towards anti-psychotic drugs than the general public. In particular the risk of dependency was assessed as 'low' by caregivers (80%), in contrast to only 18% of the general population sample. It was concluded that effective management of side effects play a vital aspect of patient career and caregivers need to be aware that their mentally ill patients are likely to be confronted with extremely negative public attitudes towards antipsychotic medication and with strong pressure to stop taking their medication in the event of side-effects[54].

Kirgaval RS, Revanakar S, Srirangapattna C (2015) conducted study was on January 15, 2009 New England Journal of Medicine addressing the use of atypical, antipsychotic drugs which carried a risk of sudden cardiac death. Atypical antipsychotic are indicated for the treatment of refractory schizophrenia, and in some cases, bipolar disorders; they are also used off-label for symptoms such as agitation, anxiety, psychotic episodes, and obsessive behaviours, as well as in children and the elderly. The findings was done on a recent meta-analysis of 150 double-blind, randomized controlled trials (N = 21,533) raised questions about the notion that atypical antipsychotic as a class are truly superior to typical antipsychotic in terms of efficacy and side-effects. It was concluded that he older agents have been associated with adverse effects such as extra pyramidal symptoms, severe movement disorders, and sudden cardiac death, among others[55].

Kung W. (2015) conducted study was conducted on extra pyramidal side effects such as Dystonias, Parkinsonism, and Akathisia. Dystonias are prolonged and unintentional muscular contractions of voluntary or involuntary muscles. Neuroleptic-induced Parkinsonism is characterized by the triad of tremor, rigidity, and bradykinesia; Akathisia is characterized by a patient's subjective sense of restlessness, along with such objective evidence of restlessness as pacing or rocking. Extra pyramidal side effects were done on

random sampling of about 100 patients receiving antipsychotics. 40% of them reported with dystonia and manifested, albeit laryngeal dystonia or dystonias of other musculature related to breathing. 30% manifested with severe muscular rigidity, fever, an altered level of consciousness, and autonomic instability characterize neuroleptic malignant syndrome. 20% of them reported with akathesia and 10% with Tardive dyskinesia[56].

Anvar Sadath, D. Muralidhar, Shivarama Varambally, Justin P. Jose, and B. N. Gangadhar (2015) Family interventions have produced benefits on clinical and family outcomes in long standing psychosis. However, little is known about the efficacy of such interventions in the early stages of psychosis. This article reviews published research over the last two decades on family intervention in first-episode psychosis. Electronic databases, such as Pub Med, Psyc INFO, and Science Direct, have been systematically searched. In addition, an exhaustive Internet search was also carried out using Google and Google Scholar to identify the potential studies that evaluated family interventions in first-episode psychosis. We have identified seven reports of five randomized controlled trials (RCTs) and five non-randomized and uncontrolled studies of family intervention. Our review on 12 reports of family intervention studies has shown mixed effects on outcomes in first-episode psychosis. Most of the reports showed no added benefits or very short-term benefits on primary clinical or family outcome variables. There is a dearth of family intervention studies in first-episode psychosis. More RCTs are needed to reach reliable conclusions[57].

Astrid M van Strien, Carolina JPW Keijsers, Hieronymus J Derijks, Rob J van Marum (2015) investigated on rating scales to measure side effects of antipsychotic medication: A systematic review In total, 52 different scales were used in the 440 articles retrieved. For multiple side effects measured with one scale, the Udvalg for Kliniske Under søgelser Side Effects Rating Scale for Clinicians was used the most, whereas the Liverpool University Neuroleptic Side Effect Rating Scale had the best psychometric characteristics (Cronbach's

α 0.81 and test–retest reliability 0.89). The Simpson Angus Scale was used the most to rate extra pyramidal side effects, although the Maryland Psychiatric Research Centre scale had the best characteristics (Cronbach's α 0.80, test–retest reliability 0.92 and inter-rater reliability 0.81–0.90). The Arizona Sexual Experience Scale was used the most to assess sexual dysfunction, but the Antipsychotics and Sexual Functioning Questionnaire and the Nagoya Sexual Functioning Questionnaire had the best characteristics[58]

Nicholas J. K. Breitbordel*, Emily K. Bell, David Dawley (2015) study is to present clinical and cost outcome data with regard to a first-episode psychosis treatment centre within the American mental health system: the Early Psychosis Intervention Centre (EPICENTER).Methods: Sixty-eight consecutively enrolled individuals with first-episode psychosis completed assessments of symptomatology, social functioning, educational/vocational functioning, cognitive functioning, substance use, and service utilization upon enrolment in EPICENTER and after 6 months of EPICENTER care. All participants were provided with access to a multi-component treatment package comprised of cognitive behavioural therapy, family psycho education, and Meta cognitive remediation. It reveals that over the first 6 months of EPICENTER care, participants experienced improvements in symptomatology, social functioning, educational/vocational functioning, cognitive functioning, and substance abuse. The average cost of care during the first 6 months of EPICENTER participation was lower than the average cost during the 6-months prior to joining EPICENTER. These savings occurred despite the additional costs associated with the receipt of EPICENTER care and were driven primarily by reductions in the utilization of inpatient psychiatric services and contacts with the legal system[59].

Nevena Divac, Milica Prostran, Igor Jakovcevski, and Natasa Cerovac (2014) Numerous studies have examined the incidence and severity of extra pyramidal syndrome with first- and second-generation antipsychotics. The majority of these studies clearly indicate that extra pyramidal syndrome

does occur with second-generation agents, though in lower rates in comparison with first generation. Risk factors are the choice of a particular second-generation agent (with Clozapine carrying the lowest risk and Risperidone the highest), high doses, history of previous extra pyramidal symptoms, and co-morbidity. Also, in comparative studies, the choice of a first-generation comparator significantly influences the results. Extra pyramidal syndrome remains clinically important even in the era of second-generation antipsychotics. The incidence and severity of extra pyramidal syndrome differ amongst these antipsychotics, but the fact is that these drugs have not lived up to the expectation regarding their tolerability[60].

Dr. Avinash De Sousa (2013) examined a cohort of patients of first episode schizophrenia, in a ten-year follow up study, for the presence of EPS. We assessed patients who had shown clinical recovery at the end of ten years of treatment. These patients were assessed for psychopathology using the PANSS, level of functioning by GAF, cognition by WMS and presence of EPS by AIMS. The present study show that abnormal EPS in first episode schizophrenia is present in 5% of patients at baseline, and 35.4% after 10 ten years. Patients in both groups of normal EPS and abnormal EPS showed equal clinical recovery on all parameters. Patients' EPS symptoms at end point did not show any correlation with any end point clinical, social and cognitive parameters. We conclude that there is low incidence of EPS in the early phase of schizophrenia; however, EPS occur in about a third of all the patients after long term ten years treatment. EPS is not found to be correlated to level of psychopathology, and it does not correlate with any of the clinical and social outcome parameters[61]

Julio Armijo, Emmanuel Méndez, Ricardo Morales, Sara Schilling, Ariel Castro, Rubén Alvarado (2013) conducted a compiles and synthesizes available scientific evidence from the last 14 years on the effectiveness of community intervention strategies for schizophrenia and related psychotic disorders. Sixty-six articles were reviewed. Community

strategies for integrated treatment from the first outbreak of schizophrenia significantly reduced negative and psychotic symptoms, days of hospitalization, and co morbidity with substance abuse and improved global functioning and adherence to treatment. In other stages, there were improved outcomes in negative and positive symptoms and general psychopathology. Psycho education for patients and families reduced the levels of self-stigma and domestic abuse, as well as improved knowledge of the disease and treatment adherence. Training focused on cognitive, social, and labour skills has been shown to improve yields in social functioning and employment status[62].

Peter M Haddad, Amlan Das, Sarvenaz Keyhaniand Imran B Chaudhry (2012) determined whether the risk of extra pyramidal side effects (EPS) differed between antipsychotic drugs used in first episode psychosis (FEP). We identified 11 RCTs comparing two or more antipsychotics in FEP and reporting on EPS. All trials assessed one or more second generation antipsychotics (SGAs), one assessed chlorpromazine, one zuclopenthixol and seven trials assessed haloperidol. Assessment and reporting of EPS varied. Compared with one or more SGA comparators, haloperidol was associated with significantly higher rates/severity of parkinsonism (seven trials) and Akathisia (six trials) and greater use of anti cholinergics (five trials) and beta-blockers (two trials). Two trials with low-dose haloperidol (≤ 4 mg) showed significantly worse EPS outcomes versus a SGA. Two of four long-term haloperidol trials (≥ 1 year) found a higher Dyskinesia-risk with haloperidol versus Olanzapine and Risperidone respectively; the remaining two trials found no difference (various SGA comparators). There was an EPS advantage for Clozapine versus chlorpromazine (one trial) and Risperidone versus Zuclopenthixol (one trial). There was little evidence of EPS-differences between SGAs, possibly reflecting use of low doses[63].

René S Kahn*, W Wolfgang Fleisch hacker*, Han Boter, Michael Davidson (2008) investigated on open randomised controlled trial of haloperidol versus second-generation antipsychotic drugs in 50 sites, in 14

countries. Eligible patients were aged 18–40 years, and met diagnostic criteria for schizophrenia, schizophrenic form disorder, or schizoaffective disorder. 498 patients were randomly assigned by a web-based online system to haloperidol (1–4 mg per day; n=103), Amisulpride (200–800 mg per day; n=104), Olanzapine (5–20 mg per day; n=105), Quetiapine (200–750 mg per day; n=104), or Ziprasidone (40–160 mg per day; n=82); follow-up was at 1 year. The primary outcome measure was all-cause treatment discontinuation. Patients and their treating physicians were not blinded to the assigned treatment[64].

Chouinard G, Margolese HC.(2005) The Extra pyramidal Symptom Rating Scale (ESRS) was developed to assess four types of drug-induced movement disorders (DIMD): Parkinsonism, Akathisia, Dystonia, and Tardive Dyskinesia (TD). Comprehensive ESRS definitions and basic instructions are given. Factor analysis provided six ESRS factors: 1) Hypokinetic Parkinsonism; 2) Orofacial Dyskinesia; 3) trunk/limb Dyskinesia; 4) Akathisia; 5) tremor; and 6) Tardive Dystonia. Two pivotal studies found high inter-rater reliability correlations in both antipsychotic-induced movement disorders and idiopathic Parkinson disease. For inter-rater reliability and certification of raters, >or=80% of item ratings of the complete scale should be +/-1 point of expert ratings and >or=70% of ratings on individual items of each ESRS subscale should be +/-1 point of expert ratings. During a cross-scale comparison, AIMS and ESRS were found to have a 96% (359/374) agreement between TD-defined cases by DSM-IV TD criteria. Two recent international studies using the ESRS included over 3000 patients worldwide and showed an incidence of TD ranging from 10.2% (2000) to 12% (1998). ESRS specificity was investigated through two different approaches, path analyses and ANCOVA PANSS factors changes, which found that ESRS measurement of drug-induced EPS is valid and discriminative from psychiatric symptoms[65].

D.N.Mendhekar, R.C.Jiloha, M.M.Mehndiratta & L.War (2002) investigated several reports available on neuroleptic malignant syndrome

(NMS) associated with risperidone but when a more stringent criterion is applied there are only a few. Report on challenge and re-challenge with various atypical antipsychotic drugs in re-emergence of post NMS psychosis is scanty. Our aim of presenting this is to highlight the differential response of various atypical antipsychotic drugs in the treatment of post NMS psychosis. This paper reports a young male with mild mental retardation who developed NMS on a low dose of nspendone. Earlier he was on haloperidol 10 mg. which was stopped 10 days prior to initiation of risperidone therapy. Symptoms of NMS resolved within 36 hours with bromocnptine; but the patient relapsed to psychosis. Re-challenge with risperidone 1mg resulted in a dystonic reaction, with clozapine 12.5 mg he developed marked sedation, hypotension and urinary incontinence. Ultimately post NMS psychosis responded well to olanzapine 10 mg and there was no recurrence of NMS. Olanzapine may be the better choice for the treatment of post NMS psychosis[66].

2.2 CONCEPTUAL FRAME WORK

Modified Orlando's Theory of Deliberative Nursing Process (1990)

Orlando was one of the earliest nurse theorist and one of the first people to develop nursing inductively from the empirical study of nursing practice. Orlando's theory has radically shifted the nurse's focus from medical diagnosis, to the nursing diagnosis that is finding and meeting the client's immediate needs.

Orlando's nursing process is composed of the following basic elements

1. Care givers(client's) behaviour
2. Reaction of the nurse
3. The Nursing activities which are designed for the clients distress

Orlando says that nurses should help in relieving the physical and mental discomfort and should not add to the client's distress.

In this theory, nursing process is used by nurses to meet the care givers (clients) needs. Meeting the needs improves the anti psychotics drugs

consuming people behaviour. The behaviour may be problems in speaking, memory, making decisions, fluctuations in mood, loss of interest in hobbies and activities.

Nurse reacts to the client's behaviour and act accordingly. After completion, the nursing action is evaluated for its effectiveness.

Patient(caregivers of patients on antipsychotic drugs) Behaviour

Care givers have inadequate knowledge in identifying extra pyramidal symptoms, which are side effects of anti psychotics.

Nurse Reaction

Nurse perceives the care givers of patients on antipsychotics behaviour (demographic variable) and feels that the care givers has some needs to be met validating the same by communicating with the client. The nurse investigator assesses the pre assessment level and post assessment level of knowledge by modified standard questionnaire.

Nurse Action

Deliberative nurse actions involving exploring the meaning and identify the extra pyramidal symptoms among the care givers of patients on anti psychotics and actions are evaluated for effectiveness after completion (post test).

In deliberative nurse actions involves exploring the meaning (verifying) and identifying the need of the care givers. The nurse investigator's activity is in planning and implementing the nursing action for meeting the care givers needs or improving the care givers behaviour (improve knowledge on extra pyramidal symptoms). Here the nurse action is applying psycho education on identification of extra pyramidal symptoms for 7 days period of time. After that post assessment was done to find out effectiveness of nurse action. If there is marked improvement in knowledge advise them to give adequate care to the clients who receiving anti psychotics, or reduction in knowledge go back for further process.

CHAPTER-III

METHODOLOGY

This chapter explains the methodology in detail. It includes research design, setting of the study, sampling technique, tools, pilot study, data collection process and plan for the data analysis. The study was conducted to assess the effectiveness of psycho education module on improving knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai.

3.1 Research approach

Quantitative approach.

3.2 Research Design: Pre experimental, one group pre test post test research design without control group and randomization.

Group	**Pre-test**	**Intervention**	**Post-test**
Caregivers of patients receiving antipsychotics attending the OPD at IMH, Chennai	**0_1**	**X**	**0_2**

Key words:

0_1=Pre-test knowledge of extra pyramidal symptoms among caregivers of patients receiving antipsychotics.

X= Psycho education module on knowledge regarding extra pyramidal symptoms.

0_2= Post-test knowledge of extra pyramidal symptoms among caregivers of patients receiving antipsychotics.

DATA COLLECTION PERIOD:

The study was conducted for four weeks from 02.01.2018 to 29.01.2018

DESCRIPTION OF VARIABLE:

INDEPENDENT VARIABLE:

Psycho education module on knowledge regarding extra pyramidal symptoms by anti psychotics.

DEPENDENT VARIABLE:

Knowledge of extra pyramidal symptoms among caregivers of patients receiving antipsychotics

3.3 Study setting

This study was conducted in Psychiatric outpatient department at Institute of Mental Health, Chennai. Institute of Mental Health is involved in Mental Health care for the past 206 Years. Founded in 1794 as an asylum to manage 20 patients, it has grown into an Institute with bed strength of 1800 patients. Special service like rehabilitation service, industrial therapy, occupational therapy, recreational therapy, family therapy, yoga, etc are available in this institution and are given separately for male and female patients, hospital runs OPD (outpatient department) under 6 units by the eminent psychiatrist and on average 580-600 patients receive mental health outpatient service per day.

3.4 Study Population:

Target population:

Caregivers of patients attending OPD, IMH at Chennai.

Accessible population

Caregivers of patients receiving antipsychotics in attending OPD, IMH at Chennai.

3.5 Sample:Care givers of anti psychotic drugs.

3.6 Sample size: 60.

3.7 Sampling technique: Convenient sampling technique.

3.8 Research variables:

Independent Variable - Psycho Education Module

Dependent Variable - Knowledge Regarding EPS among Caregivers

3.9 Criteria for sample selection:-

3.9.1. (a) Inclusion Criteria:

1. Caregivers who are willing to participate in the study.
2. Both male and female who are willing to participate in the study.

Caregivers who are able to read and write Tamil and English.

3.9.1. (b) Exclusion Criteria:-

1. care givers Who are not available during my data collection.

2.Caregivers who are all not able to followup regularly.

Development and Description of the tool

Development of Tool:

Tool was selected after extensive literature review from the various text book, internet search, guidance and discussion with experts in the field of nursing, psychiatry and statistics. A structured questionnaire was used to collect data from the caregivers regarding extra pyramidal symptoms who were attending OPD in Institute of mental health, Chennai.

3.10 Tool For Data Collection

The tool consists of Section A and B. It is divided into two parts.

3.10.1 Part-A:

Demographic data which consists of age, sex, marital status, education.

3.10.2 Part-B:

MGASS will be used to assess the level of knowledge of caregivers regarding extra pyramidal symptoms and after administering MGASS description programme after 7 days, post test knowledge will be assessed.

3.11 Content Validity

Data collection tool is an instrument that measures the variables of interest of the study accurately, precisely and sensitively. Content validity of the tool was obtained from experts in the field of psychiatric nursing, psychiatry, psychology and statistical expert. The experts were an associate professor, psychiatrist and clinical psychologist. The experts were requested to check the relevance, sequence and adequacy of the content. There was uniform agreement of the tool which is adopted to conduct the study. Hence, the investigator precedes the same tool.

3.12 Ethical Consideration

The study objectives, intervention, data collection procedure approved by the Ethical Committee of Madras Medical College, Chennai. The caregivers regarding extra pyramidal symptoms were explained about the purpose and need for the study. They were assured that their details and answers will be used only for the research purpose. Further they were ensured that their details will be kept confidentially. Thus the investigator followed the ethical guidelines, which were issued by the Ethical Committee after getting a written permission.

3.13. Pilot Study

Pilot study is a trail run for the main study to test the reliability, practicability and feasibility of the study. The main objectives of the pilot study are to help the researcher to become familiar with the use of tool and to find out the difficulties in the main study. The pilot study was conducted after getting ethical clearance and the permission from the Institute of mental health, Chennai. It was conducted for a period of one week from. Sample of 10 caregivers regarding extra pyramidal symptoms were selected by convenient sampling technique. Informed consent was obtained from them before collection of the data. Data were collected from the caregivers regarding extra pyramidal symptoms by structured questionnaire before the implementation of psycho education. After completion of psycho education sessions, the caregivers regarding extra pyramidal symptoms were assessed their clients symptoms of EPS by using same scale. Pilot study samples are excluded in the main study.

3.14 Reliability of the Tool

After pilot study reliability of the tool was assessed by using split - half method. The 'r' value obtained was 0.85 which showed a high positive correlation. Hence the tool was considered reliable.

3.15 METHOD OF DATA COLLECTION:

Setting of the study:

The study will be conducted in OPD, in IMH, Chennai. It is a 1800 bedded hospital which is located at 7km distance away from College of Nursing. Prior to data collection, permission will be obtained from the concerned authority. After obtaining the consent the investigator will explain the purpose of the study to the subjects by structured interview schedule and structured knowledge questionnaire will be administered, followed by a psycho education module and post test will be assessed after 2 weeks.

The entire data collection procedure was spread out over a period of four weeks from 02-01-2018 to 29-01-2018.There are daily 200-300 male and female caregivers of age group from 20 to 50 years, irrespective of caste, creed and religion. Initially the investigator approaches each female clients after getting permission from the Director.

Investigator selected 70 care givers initially. In that 2 of them were dropped due to chronic illness, 3 of them were unable to attend due to their physical inability and 5 were not willing to participate in the study. The investigator selected 60 care givers as per the inclusion and exclusion criteria. The care givers were introduced with the whole programme after an introduction and then a written informed consent was obtained from them for willingness to participate in the study. They were assured that their responses and details will be kept confidential and will be used only for the research purpose. Before the tool was administered some informal discussion were made with participants to establish rapport so that they would be relaxed.

3.16 Intervention Protocol

The total 60 male and female care givers were divided into two groups. Each group contained 30 people. Every day the participants were gathered around 7AM in the common hall. In the first two days pre test questionnaire was administered to them and they were asked to give appropriate answers for all statements to find out the level of knowledge regarding EPS by MGASS description Marks Value. Following assessment two weeks of psycho education on care of EPS, Before starting psycho education the researcher were introduced herself to the care givers and asked the care givers to introduce themselves. Every day psycho education started with morning session from 8 a.m. to 10 a. m. After the psycho education post test was done by modified Glascow Antipsychotics side effect scale to assess the knowledge level of caregivers.

3.17 Data entry and Data Analysis:-

The data obtained will be analyzed in terms of objectives of the study using descriptive and inferential statistics.

1) **Descriptive statistics:**

- Frequency and percentage distribution will be used to analyze the demographic variables of caregivers.
- Mean and standard deviation will be used to analyze the level of knowledge among caregivers.

2) **Inferential statistics:-**

- Paired't' test will be used to find out the significant difference between the mean pretest and post test knowledge score of caregivers.
- Chi square test will be used to find out the level of knowledge with selected demographic variables.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

This chapter deals with analysis and interpretation of the collected data from 60 caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai. The purpose of the analysis is to convert the collected data to an interpreted meaningful form,so that the results can be found and association can be identified.Statistical analysis helps the researcher to make sense of quantitative information. Statistical procedure enables the researcher to summarize,organize,evaluate,interpret&communicate numeric information.

The collected data were tabulated and presented according to the objectives under the following headings

- ✓ **Section I:**

  Deals with the socio demographic variables

- ✓ **Section II:**

  Assess the pretest knowledge of caregiver regarding extra pyramidal symptoms.

- ✓ **Section III:**

  Assess the posttest knowledge of caregiver regarding extra pyramidal symptoms.

- ✓ **Section IV:**

  Assess the effectiveness of psycho education module.

- ✓ **Section V:**

  Association between posttest knowledge score and selected demographic variables.

Section I: Table 4.1 - Socio demographic variables of care givers.

Demographic variables		No. of caregivers	%
Age	21 -30 years	38	63.3%
	31 -40 years	13	21.7%
	41 -50 years	6	10.0%
	51 -60 years	3	5.0%
Sex	Male	40	66.7%
	Female	20	33.3%
Living area	Rural	35	58.3%
	Urban	20	33.4%
	Semi urban	5	8.3%
Marital status	Married	36	60.0%
	Unmarried	19	31.7%
	Widow	5	8.3%
	Others	0	0.0%
Occupation status	Cooly	30	50.0%
	Business	22	36.6%
	State government	7	11.7%
	Central government	1	1.7%
Type of Family	Joint family	19	31.6%
	Nuclear family	31	51.7%
	Extended family	10	16.7%
Income of the family	Rs 5001- 10,000	30	50.0%
	Rs 10,001- 20,000	18	30.0%
	Rs 20,001- 30,000	6	10.0%
	>Rs 30,000	6	10.0%
Years of getting treatment for	1- 5 years	24	40.0%
	6 -10 years	21	35.0%

psychosis	11- 15 years	10	16.7%
	> 15 years	5	8.3%
Side effects of antipsychotics are	Drawling of saliva	21	35.0%
	Rigidity of body and neck	26	43.3%
	Eye balls moves up	10	16.7%
	Fever with palpitation	3	5.0%
EPS means	Extra psychiatric symptoms	26	43.3%
	Extra pyramidal symptoms	21	35.0%
	Extra pyramidal syndrome	9	15.0%
	Extra six symptoms	4	6.7%
Treatment measure for EPS is	Getting treatment in psychiatric OPD	30	50.0%
	Getting local traditional treatment	18	30.0%
	Getting black magic treatment	6	10.0%
	Stop to attending psychiatric OPD	6	10.0%

The above table 4.1 shows the demographic information of care givers those who are participated for the following study on "Assess the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai".

Among 60 caregivers (63.3%) were 21-30 years, (21.7%) were 31-40 years, (10%) were 41-50 years, (5%) were 51-60 years.

In case of sex (66.7%) were males, (33.3%) were females.

According to living area (58.3%) were from rural, (33.4%) were from urban, (8.3%) were from semi urban.

In marital status (60%) were married, (31.7%) were unmarried, (8.3%) were widow, and none of them in other categories.

According to occupation status (50%) were cooly, (36.6%) were doing business, (11.7%) were state government employee, (1.7%) were central government employee.

The type of family revealed that (51.7%) were nuclear family, (31.6%) were joint family, and (16.7%) were extended family.

Regarding income of the family (50%) were earned Rs. 5001-10,000, (30%) were earned Rs. 10,001-20,000, (10%) Rs. 20,001-30,000, (10%) were earned more than 30,000.

According to years of getting treatment for psychosis (40%) were 1-5 years, (35%) were 6-10 years, (16.7%) were 11-15 years and (8.3%) were more than 15 years.

Knowledge regarding side effects of antipsychotics was (43.3%) thought rigidity of body and neck, (35%) thought drawling of saliva, (16.7%) thought eye balls moves up, (5%) thought fever with palpitation.

Caregiver knowledge about EPS means was (43.3%) were thought extra psychiatric symptoms, (35%) were thought extra pyramidal, (15%) were extra pyramidal syndrome, (6.7%) were thought extra six symptoms.

Caregiver knowledge about treatment measure for EPS is (50%) were thought getting treatment in psychiatric OPD, (30%) were thought getting local traditional treatment, (10%) getting black magic treatment, (10%) were thought stop to attending psychiatric OPD.

Section II: Assess the pretest knowledge of caregiver regarding extra pyramidal symptoms.

Table 2: Each question wise pretest level of knowledge score

S.No.	Questions	Never	Once	A few times	Every day
		0	**1**	**2**	**3**
1	Is your relative felt sleepy during the day	0	40	18	2
2	Is your relative felt drugged or like a zombie	0	39	20	1
3	Is your relative felt dizzy when they stood up and/or have fainted	0	35	23	2
4	Is your relative felt heart beating irregularly or unusually fast	1	24	32	3
5	Is your relative muscles have been tense or jerky	2	23	30	5
6	Is your relative hands or arms have been shaky	2	24	25	9
7	Is your relative legs have felt restless and/or they couldn't sit still	6	31	15	8
8	Is your relative have been drooling	0	30	18	12
9	Is your relative movements or walking have been slower than usual	1	31	20	8
10	Is your relative have had, or people have noticed uncontrollable movements of their face or body	2	28	26	4
11	Is your relative vision has been blurry	8	26	20	6
12	Is your relative mouth has been dry	4	35	19	2
13	Is your relative have had difficulty passing urine	2	31	21	6
14	Is your relative have felt like they going to be sick or have vomited	4	35	15	6
15	Is your relative have wet the bed	7	24	24	5
16	Is your relative have been very thirsty and/or passing urine frequently	2	31	22	5

17	The areas around their nipples have been sore and wollen	9	28	17	6
18	Is your relative have noticed fluid coming from my nipples	13	28	14	5
19	Is your relative have had problems enjoying sex	16	22	17	5
20	Men only: have had problems getting an erection	33	12	10	5
21	Women only: Is your relative have noticed a change in their periods	45	0	0	15
22	Men and women: Is your relative have been gaining weight	40	0	0	20

Table 4.3: Each question wise pretest percentage of knowledge score of care giver regarding extra pyramidal symptoms

S.No.	Questions	Maximum score	Mean score	SD	% of mean score
1	Is your relative felt sleepy during the day	3	1.37	.55	45.67%
2	Is your relative felt drugged or like a zombie	3	1.37	.52	45.67%
3	Is your relative felt dizzy when they stood up and/or have fainted	3	1.45	.57	48.33%
4	Is your relative have felt their heart beating irregularly or unusually fast	3	1.62	.61	54.00%
5	Is your relative muscles have been tense or jerky	3	1.63	.69	54.33%
6	Is your relative hands or arms have been shaky	3	1.68	.77	56.00%
7	Is your relative legs have felt restless and/or they couldn't sit still	3	1.42	.85	47.33%
8	Is your relative have been drooling	3	1.70	.79	56.67%
9	Is your relative movements or walking have been slower than usual	3	1.58	.74	52.67%
10	Is your relative have had, or people have noticed uncontrollable movements of my face or body	3	1.53	.68	51.00%
11	Is your relative vision has been blurry	3	1.40	.85	46.67%
12	Is your relative mouth has been dry	3	1.32	.65	44.00%

13	Is you relative have had difficulty passing urine	3	1.52	.72	50.67%
14	Is your relative have felt like going to be sick or have vomited	3	1.38	.76	46.00%
15	Is your relative have wet the bed	3	1.45	.81	48.33%
16	Is your relative have been very thirsty and/or passing urine frequently	3	1.50	.70	50.00%
17	The areas around their nipples have been sore and swollen	3	1.33	.86	44.33%
18	Is your relative have noticed fluid coming from their nipples	3	1.18	.87	39.33%
19	Is your relative have had problems enjoying sex	3	1.18	.93	39.33%
20	Men only: Is your relative have had problems getting an erection	3	.78	1.01	26.00%
21	Women only: Is your relative have noticed a change in their periods	3	.75	1.31	25.00%
22	Men and women: Is your relative have been gaining weight	3	1.00	1.43	33.33%
	Overall	66	30.15	4.68	45.68%

Table 4.4: Pretest level of knowledge score

Level of knowledge	No. of caregivers	%
Good	0	0.0%
Moderate	16	26.7%
Poor	44	73.3%
Total	60	100%

The above table 4.4 shows the pretest level of knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs Using Glasgow Antipsychotic Side-effect Scale (GASS).

In general, none of the caregivers are having good level knowledge score, 26.7% are having Moderate level knowledge score and 73.3% of them having poor level of knowledge score on extra pyramidal symptoms

GASS score interpretation:

0 – never 1-Once 2 – few times 3 - everyday

Min=0 Max=3 Total questions=22 Maximum marks= 66

S No.	Grade	Score
1.	Good	0 – 12
2.	Moderate	13 – 26
3.	Poor	>26

Scoring patters

1. Allow the patient to fill in the questionnaire themselves.

Questions 1-20 relate to the previous week and questions 21-22 to the last three months.

2. Scoring For questions 1-20 award 1 point for the answer "once", 2 points for the answer "a few times" and 3 points for the answer "everyday". Please note zero points are awarded for an answer of "never".

For questions 21 and 22 award 3 points for a "yes" answer and 0 points for a "no". Total for all questions= 3.

For male and female patients a total score of: 0-12 = absent/mild side effects 13-26 = moderate side effects over 26 = severe side effects

Section III: Assess the posttest knowledge of caregiver regarding extra pyramidal symptoms.

Table 4.5: Each question wise posttest level of knowledge score

S.No.	Questions	Never	Once	A few times	Every day
		0	1	2	3
1	Is your relative felt sleepy during the day	14	42	4	0
2	Is your relative felt drugged or like a zombie	14	42	4	0
3	Is your relative felt dizzy when they stood up and/or have fainted	27	33	0	0
4	Is your relative have felt their heart beating irregularly or unusually fast	30	29	1	0
5	Is your relative muscles have been tense or jerky	42	15	3	0
6	Is your relative hands or arms have been shaky	39	20	1	0
7	Is your relative legs have felt restless and/or they couldn't sit still	37	22	1	0
8	Is your relative have been drooling	38	19	3	0

9	Is your relative movements or walking have been slower than usual	32	25	3	0
10	Is your relative have had, or people have noticed uncontrollable movements of their face or body	30	27	3	0
11	Is your relative vision has been blurry	25	33	2	0
12	Is your relative mouth has been dry	27	31	2	0
13	Is your relative have had difficulty passing urine	29	29	2	0
14	Is your relative have felt like going to be sick or have vomited	28	32	0	0
15	Is your relative have wet the bed	24	35	1	0
16	Is your relative have been very thirsty and/or passing urine frequently	26	33	1	0
17	The areas around their nipples have been sore and woollen	25	32	3	0
18	Is your relative have noticed fluid coming from their nipples	21	37	2	0
19	Is your relative have had problems enjoying sex	17	42	1	0
20	Men only: Is your relative have had problems getting an erection	27	33	0	0
21	Women only: Is your relative have noticed a change in they periods	57	3	0	0
22	Men and women: Is your relative have been gaining weight	59	1	0	0

Table 4.6: Each question wise posttest percentage of knowledge score

S.No.	Questions	Maximum score	Mean score	SD	% of mean score
1	Is your relative felt sleepy during the day	3	.93	.45	31.00%
2	Is your relative felt drugged or like a zombie	3	.93	.45	31.00%
3	I felt dizzy when they stood up and/or have fainted	3	.65	.48	21.67%
4	Is your relative have felt their heart beating irregularly or unusually fast	3	.62	.52	20.67%
5	Is your relative muscles have been tense or jerky	3	.45	.59	15.00%
6	Is your relative hands or arms have been shaky	3	.47	.54	15.67%
7	Is your relative legs have felt restless and/or they couldn't sit still	3	.50	.54	16.67%
8	Is your relative have been drooling	3	.52	.60	17.33%
9	Is your relative movements or walking have been slower than usual	3	.62	.58	20.67%
10	Is your relative have had, or people have noticed uncontrollable movements of their face or body	3	.65	.58	21.67%
11	Is your relative vision has been blurry	3	.72	.52	24.00%
12	Is your relative mouth has been dry	3	.68	.54	22.67%
13	Is your relative have had difficulty passing urine	3	.65	.55	21.67%
14	Is your relative have felt like going to be sick or have vomited	3	.63	.49	21.00%
15	Is your relative have wet the bed	3	.72	.49	24.00%
16	Is your relative have been very thirsty and/or passing urine frequently	3	.67	.51	22.33%
17	The areas around their nipples have been sore and wollen	3	.73	.55	24.33%
18	Is your relatives have noticed fluid coming from their nipples	3	.77	.50	25.67%

19	Is your relative have had problems enjoying sex	3	.82	.43	27.33%
20	Men only: Is your relative have had problems getting an erection	3	.65	.48	21.67%
21	Women only: Is your relative have noticed a change in their periods	3	.15	.36	5.00%
22	Men and women: Is your relative have been gaining weight	3	.12	.32	4.00%
	Overall	66	13.63	2.96	20.65%

Table 4.7: Posttest level of knowledge score

Level of knowledge	**No. of caregivers**	**%**
Good	23	38.3%
Moderate	37	61.7%
Poor	0	0.0%
Total	**60**	**100%**

The above table 4.7 shows the posttest level of knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs Using Glasgow Antipsychotic Side-effect Scale (GASS).

In general 38.3% of the caregivers are having good level knowledge score, 61.7% are having Moderate level knowledge score and none of them having poor level of knowledge score on pyramidal symptoms.

Section IV: Assess the effectiveness of psycho education module.

Table 4.8: Comparison of pretest and posttest knowledge score

S. No.	Knowledge on	Pretest		Posttest		Mean Difference	Student's paired t-test
		Mean	SD	Mean	SD		
1	Is your relative felt sleepy during the day	1.37	.55	.93	.45	0.44	t=4.65P=0.001 *** DF= 59 , Significant
2	Is your relative felt drugged or like a zombie	1.37	.52	.93	.45	0.44	t=4.81 P=0.001 *** DF= 59 , Significant
3	Is your relative felt dizzy when they stood up and/or have fainted	1.45	.57	.65	.48	0.8	t=9.40 P=0.001 *** DF= 59 , Significant
4	Is your relative have felt their heart beating irregularly or unusually fast	1.62	.61	.62	.52	1	t=9.18 P=0.001 *** DF= 59 , Significant
5	Is your relative muscles have been tense or jerky	1.63	.69	.45	.59	1.18	t=11.27P=0.00 1 *** DF= 59 , Significant
6	Is your relative hands or arms have been shaky	1.68	.77	.47	.54	1.21	t=10.89 P=0.001 *** DF= 59 , Significant

7	Is your relative legs have felt restless and/or they couldn't sit still	1.42	.85	.50	.54	0.92	t=6.78 P=0.001 *** DF= 59 , Significant
8	Is your relative have been drooling	1.70	.79	.52	.60	1.18	t=9.01 P=0.001 *** DF= 59 , Significant
9	Is your relative movements or walking have been slower than usual	1.58	.74	.62	.58	0.96	t=8.88 P=0.001 *** DF= 59 , Significant
10	Is your relative have had, or people have noticed uncontrollable movements of their face or body	1.53	.68	.65	.58	0.88	t=8.09 P=0.001 *** DF= 59 , Significant
11	Is your relative vision has been blurry	1.40	.85	.72	.52	0.68	t=5.38 P=0.001 *** DF= 59 , Significant
12	Is your relative mouth has been dry	1.32	.65	.68	.54	0.64	t=6.28 P=0.001 *** DF= 59 , Significant
13	Is your relative have had difficulty passing urine	1.52	.72	.65	.55	0.87	t=7.52 P=0.001 *** DF= 59 , Significant
14	Is your relative have felt like going to be sick or have vomited	1.38	.76	.63	.49	0.75	t=7.12 P=0.001 *** DF= 59 , Significant

15	Is your relative have wet the bed	1.45	.81	.72	.49	0.73	t=6.75 P=0.001 *** DF= 59 , Significant
16	Is your relative have been very thirsty and/or passing urine frequently	1.50	.70	.67	.51	0.83	t=7.81 P=0.001 *** DF= 59 , Significant
17	The areas around their nipples have been sore and swollen	1.33	.86	.73	.55	0.6	t=5.03 P=0.001 *** DF= 59 , Significant
18	Is your relative have noticed fluid coming from their nipples	1.18	.87	.77	.50	0.41	t=3.41 P=0.001 *** DF= 59 , Significant

***** Very high significant at P≤0.001**

The above table 4. 8 shows the comparison of pretest and posttest knowledge score.

Each question wise there is a statistically significant difference between pretest and posttest score. Significance of difference between pretest and posttest score was calculated using student paired t-test.

Table 4.9: comparison of overall knowledge score before and after psycho education module

	No. of *caregivers*	**Pretest Mean±SD**	**Posttest Mean±SD**	**Meandifference Mean±SD**	**Student'S paired t-test**
Overall Score	60	30.15 ± 4.67	13.63 ± 2.95	16.51± 4.42	t=28.91 P=0.001*** DF = 59, significant

***** Very high significant at P≤0.001**

The above table 4.9 shows the comparison of overall symptoms knowledge before and after the administration of psycho education module. On an average, in pre test caregivers are having 30.15score after the administration of psycho education module they are having 13.63 knowledge score. Difference is 16.51, this difference is statistically significant. Statistical significance was calculated by using student's paired't' test.

Table 4.10 Each question wise pretest and posttest percentage of stress

S.No.	Domains	Pretest stress	Posttest stress	% of stress reduction Score
1	Is your relative felt sleepy during the day	45.67%	31.00%	14.67%
2	Is your relative felt drugged or like a zombie	45.67%	31.00%	14.67%
3	Is your relative felt dizzy when they stood up and/or have fainted	48.33%	21.67%	26.66%
4	Is your relative have felt their heart beating irregularly or unusually fast	54.00%	20.67%	33.33%
5	Is your relative muscles have been tense or jerky	54.33%	15.00%	39.33%
6	Is your relative hands or arms have been shaky	56.00%	15.67%	40.33%
7	Is your relative legs have felt restless and/or they couldn't sit still	47.33%	16.67%	30.66%
8	Is your relative have been drooling	56.67%	17.33%	39.34%
9	Is your relative movements or walking have been slower than usual	52.67%	20.67%	32.00%
10	Is your relative have had, or people have noticed uncontrollable movements of their face or body	51.00%	21.67%	29.33%
11	Is your relative vision has been blurry	46.67%	24.00%	22.67%
12	Is your relative mouth has been dry	44.00%	22.67%	21.33%
13	Is your relative have had difficulty passing urine	50.67%	21.67%	29.00%

14	Is your relative have felt like going to be sick or have vomited	46.00%	21.00%	25.00%
15	Is your relative have wet the bed	48.33%	24.00%	24.33%
16	Is your relative have been very thirsty and/or passing urine frequently	50.00%	22.33%	27.67%
17	The areas around their nipples have been sore and woolen	44.33%	24.33%	20.00%
18	Is your relative have noticed fluid coming from their nipples	39.33%	25.67%	13.66%
19	Is your relative have had problems enjoying sex	39.33%	27.33%	12.00%
20	Men only: Is your relative have had problems getting an erection	26.00%	21.67%	4.33%
21	Women only: Is your relative have noticed a change in their periods	25.00%	5.00%	20.00%
22	Men and women: Is your relative have been gaining weight	33.33%	4.00%	29.33%
	Overall	45.68%	20.65%	25.03%

The above table 4.10 shows each question wise knowledge score among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai.

Table 4.11: Comparison of pretest and posttest level of knowledge score

Level of knowledge	Pretest		Posttest		Generalized McNemar's test
	n	%	n	%	
Good	0	0.0%	23	38.3%	χ^2=49.22 P=0.001***(S)
Moderate	16	26.7%	37	61.7%	
Poor	44	73.3%	0	0.0%	
Total	**60**	**100.0%**	**60**	**100.0%**	

***significant at p<0.001 level**

Table no.11shows the pretest and post-test level of knowledge score among caregivers Before education module, none of the caregivers are having good level knowledge score, 26.7% are having Moderate level knowledge score and 73.3% of them having poor level of knowledge score on pyramidal symptoms

After education module, 38.3% of the caregivers are having good level knowledge score, 61.7% are having Moderate level knowledge score and none of them having poor level of knowledge score on pyramidal symptoms

Level of knowledge score between pretest and posttest was calculated using Generalised McNemar's chi square test.

Table 4.12: Effectiveness and generalization of psycho education module

	Max score	Mean score	Mean symptoms knowledge score with 95% Confidence interval	Percentage of symptoms knowledge score with 95% Confidence interval
Pretest	66	30.15	16.52(15.37 – 17.66)	25.03% (23.28% – 26.75%)
Posttest	66	13.63		

The above table 4.12 shows the effectiveness of psycho education module in knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs attending outpatient department at IMH, Chennai

On an average, in posttest after having psycho education module, caregivers are having symptom reduction knowledge score 25.03% score than pretest score.

Differences and generalization of knowledge score between pretest and posttest score was calculated using and mean difference with 95% CI and proportion with 95% CI.

In this study effectiveness of the study is point estimate of 25.03% and interval estimate is 23.28% to 26.75%. It means in this similar setup of the study, whom ever conducted, 95 % we can assure, effectiveness of the study will lies between 23.28% to 26.75%symptom knowledge score.

Section V: Association between posttest knowledge score and selected demographic variables.

Table 4.13: Association between pretest level of symptom knowledge score and caregivers demographic variables.

Demographic variables		Pretest level of symptom knowledge score						n	Chi square test
		Good		Moderate		Poor			
		n	%	n	%	n	%		
Age	21 -30 years	0	0.0%	10	26.3%	28	73.7%	38	$\chi 2=2.84$ P=0.41(NS)
	31 -40 years	0	0.0%	3	23.1%	10	76.9%	13	
	41 -50 years	0	0.0%	3	50.0%	3	50.0%	6	
	51 -60 years	0	0.0%	0	0.0%	3	100.0%	3	
Sex	Male	0	0.0%	13	32.5%	27	67.5%	40	$\chi 2=2.08$
	Female	0	0.0%	3	15.0%	17	85.0%	20	P=0.14(NS)
Living area	Rural	0	0.0%	11	31.4%	24	68.6%	35	$\chi 2=2.25$
	Urban	0	0.0%	5	25.0%	15	75.0%	20	P=0.32(NS)
	Semi urban	0	0.0%	0	0.0%	5	100.0%	5	
Marriage	Married	0	0.0%	11	30.6%	25	69.4%	36	$\chi 2=2.10$
	Unmarried	0	0.0%	5	26.3%	14	73.7%	19	P=0.35(NS)
	Widow	0	0.0%	0	0.0%	5	100.0%	5	
	Others	0	0.0%	0	0.0%	0	0.0%	0	
Occupation	Cooly	0	0.0%	8	26.7%	22	73.3%	30	$\chi 2=1.21$
	Business	0	0.0%	7	31.8%	15	68.2%	22	P=0.75(NS)
	State government	0	0.0%	1	14.3%	6	85.7%	7	
	Central government	0	0.0%	0	0.0%	1	100.0%	1	

Family	Joint family	0	0.0%	3	15.8%	16	84.2%	19	$\chi 2=2.60$ P=0.27(NS)
	Nuclear family	0	0.0%	11	35.5%	20	64.5%	31	
	Extended family	0	0.0%	2	20.0%	8	80.0%	10	
Income of the family	Rs 5001-10,000	0	0.0%	8	26.7%	22	73.3%	30	$\chi 2=0.45$ P=0.92(NS)
	Rs 10,001-20,000	0	0.0%	5	27.8%	13	72.2%	18	
	Rs 20,001-30,000	0	0.0%	2	33.3%	4	66.7%	6	
	>Rs 30,000	0	0.0%	1	16.7%	5	83.3%	6	
Years of getting treatment for psychosis	1- 5 years	0	0.0%	7	29.2%	17	70.8%	24	$\chi 2=5.30$ P=0.15(NS)
	6 -10 years	0	0.0%	4	19.0%	17	81.0%	21	
	11- 15 years	0	0.0%	5	50.0%	5	50.0%	10	
	> 15 years	0	0.0%	0	0.0%	5	100.0%	5	
Side effects of antipsychotics are	Drawling of saliva	0	0.0%	6	28.6%	15	71.4%	21	$\chi 2=1.75$ P=0.62(NS)
	Rigidity of body and neck	0	0.0%	8	30.8%	18	69.2%	26	
	Eye balls moves up	0	0.0%	1	10.0%	9	90.0%	10	
	Fever with palpitation	0	0.0%	1	33.3%	2	66.7%	3	
EPS means	Extra psychiatric symptoms	0	0.0%	3	11.5%	23	88.5%	26	$\chi 2=6.06$ P=0.10(NS)
	Extra pyramidal symptoms	0	0.0%	9	42.9%	12	57.1%	21	
	Extra pyramidal syndrome	0	0.0%	3	33.3%	6	66.7%	9	
	Extra six symptoms	0	0.0%	1	25.0%	3	75.0%	4	

Treatment measure for EPS is	Getting treatment in psychiatric OPD	0	0.0%	10	33.3%	20	66.7%	30	$\chi 2=2.04$ P=0.56(NS)
	Getting local traditional treatment	0	0.0%	3	16.7%	15	83.3%	18	
	Getting black magic treatment	0	0.0%	1	16.7%	5	83.3%	6	
	Stop to attending psychiatric OPD	0	0.0%	2	33.3%	4	66.7%	6	

The above table 4.13 shows the association between pretest level of symptom knowledge and their demographic variables. None of the demographic variables are significantly associated with their pretest level of knowledge score. Statistical significance was calculated using chi square test.

Table 4.14: Association between posttest level of symptom knowledge score and caregivers demographic variables

Demographic variables		Posttest level of symptom knowledge score						N	Chi square test
		Good		Moderate		Poor			
		n	%	n	%	n	%		
Age	21 -30 years	19	50.0%	19	50.0%	0	0.0%	38	**χ2=8.10**
	31 -40 years	5	38.5%	8	61.5%	0	0.0%	13	**P=0.05*(S)**
	41 -50 years	0	0.0%	6	100.0%	0	0.0%	6	
	51 -60 years	0	0.0%	3	100.0%	0	0.0%	3	
Sex	Male	21	52.5%	19	47.5%	0	0.0%	40	**χ2=10.18**
	Female	2	10.0%	18	90.0%	0	0.0%	20	**P=0.01**(S)**
Living area	Rural	16	45.7%	19	54.3%	0	0.0%	35	χ2=2.25
	Urban	5	25.0%	15	75.0%	0	0.0%	20	P=0.32(NS)
	Semi urban	2	40.0%	3	60.0%	0	0.0%	5	
Marriage	Married	16	44.4%	20	55.6%	0	0.0%	36	χ2=2.31
	Unmarried	5	26.3%	14	73.7%	0	0.0%	19	P=0.31(NS)
	Widow	2	40.0%	3	60.0%	0	0.0%	5	
	Others	0	0.0%	0	0.0%	0	0.0%	0	
Occupation	Cooly	10	33.3%	20	66.7%	0	0.0%	30	χ2=1.73
	Business	10	45.5%	12	54.5%	0	0.0%	22	P=0.42(NS)
	State government	2	28.6%	5	71.4%	0	0.0%	7	
	Central government	1	100.0%	0	0.0%	0	0.0%	1	
Family	Joint family	3	15.8%	16	84.2%	0	0.0%	19	**χ2=6.40**
	Nuclear family	16	51.6%	15	48.4%	0	0.0%	31	**P=0.05*(S)**
	Extended family	4	40.0%	6	60.0%	0	0.0%	10	
Income of the family	Rs 5001- 10,000	9	30.0%	21	70.0%	0	0.0%	30	χ2=2.32
	Rs 10,001-20,000	9	50.0%	9	50.0%	0	0.0%	18	P=0.50(NS)

	Rs 20,001-30,000	3	50.0%	3	50.0%	0	0.0%	6	
	>Rs 30,000	2	33.3%	4	66.7%	0	0.0%	6	
Years of getting treatment for psychosis	1- 5 years	10	41.7%	14	58.3%	0	0.0%	24	**$\chi 2$=10.57 P=0.01**(S)**
	6 -10 years	8	38.1%	13	61.9%	0	0.0%	21	
	11- 15 years	4	40.0%	6	60.0%	0	0.0%	10	
	> 15 years	1	20.0%	4	80.0%	0	0.0%	5	
Side effects of antipsychotics are	Drawling of saliva	8	38.1%	13	61.9%	0	0.0%	21	$\chi 2$=2.12 P=0.54(NS)
	Rigidity of body and neck	12	46.2%	14	53.8%	0	0.0%	26	
	Eye balls moves up	2	20.0%	8	80.0%	0	0.0%	10	
	Fever with palpitation	1	33.3%	2	66.7%	0	0.0%	3	
EPS means	Extra psychiatric symptoms	11	42.3%	15	57.7%	0	0.0%	26	$\chi 2$=0.57 P=0.90(NS)
	Extra pyramidal symptoms	8	38.1%	13	61.9%	0	0.0%	21	
	Extra pyramidal syndrome	3	33.3%	6	66.7%	0	0.0%	9	

	Extra six symptoms	1	25.0%	3	75.0%	0	0.0%	4	
Treatment measure for EPS is	Getting treatment in psychiatric OPD	14	46.7%	16	53.3%	0	0.0%	30	$\chi 2=2.32$ P=0.50(NS)
	Getting local traditional treatment	6	33.3%	12	66.7%	0	0.0%	18	
	Getting black magic treatment	2	33.3%	4	66.7%	0	0.0%	6	
	Stop to attending psychiatric OPD	1	16.7%	5	83.3%	0	0.0%	6	

The above table 4.14 shows the association between posttest level of knowledge and caregivers demographic variables. Younger age caregivers, male gender caregivers, joint family caregivers, less duration of treatment patients caregiver are having more symptom reduction knowledge than others..Statistical significance was calculated using chi square test.

Table 4.15: Association between knowledge reduction score and demographic variables

Demographic variables		symptom reduction knowledge score						n	Oneway ANOVA F-test/t-test
		Pretest		Posttest		Reduction score=Post-Pre			
		Mean	SD	Mean	SD	Mean	SD		
Age	21 -30 years	30.00	4.66	11.39	3.27	18.61	4.50	38	**F=2.75P=0.05*(S)**
	31 -40 years	30.46	4.33	15.24	2.37	15.22	4.66	13	
	41 -50 years	30.17	6.74	15.17	2.40	15.00	5.32	6	
	51 -60 years	30.67	4.04	16.00	2.00	14.67	3.79	3	
Sex	Male	30.43	4.90	13.33	2.89	17.10	4.78	40	**t=2.39P=0.05*(S)**
	Female	30.60	3.91	16.40	3.08	14.20	3.59	20	
Living area	Rural	29.23	4.82	13.03	2.86	16.20	4.59	35	F=0.25 P=0.77(NS)
	Urban	31.25	4.33	14.15	2.32	17.10	4.29	20	
	Semi urban	32.20	4.21	15.80	4.82	16.40	4.39	5	
Marriage	Married	29.39	4.78	13.61	3.24	15.78	4.84	36	F=2.43 P=0.10(NS)
	Unmarried	30.74	4.23	13.79	2.64	16.95	3.39	19	
	Widow	33.40	4.72	13.20	2.39	20.20	3.11	5	
	Others	0.00	0.00	0.00	0.00	0.00	0.00	0	
Occupation	Cooly	30.67	4.33	14.27	3.19	16.40	3.69	30	F=0.27P=0.85(NS)
	Business	29.55	5.10	12.82	2.75	16.73	5.32	22	
	State government	29.86	5.55	14.00	1.83	15.86	4.98	7	
	Central government	30.00	0.00	10.00	0.00	20.00	0.00.	1	
Family	Joint family	31.95	4.13	15.05	3.10	16.89	3.78	19	**F=6.40 P=0.05*(S)**
	Nuclear family	32.70	5.08	13.50	2.88	19.20	6.14	31	
	Extended family	28.23	4.13	12.81	2.64	15.42	3.85	10	

Income of the family	Rs 5001-10,000	30.37	4.45	14.17	2.74	16.20	4.08	30	F=0.89 P=0.44(NS)
	Rs 10,001-20,000	28.94	4.29	13.06	3.30	15.89	3.71	18	
	Rs 20,001-30,000	32.00	7.24	13.00	3.95	19.00	7.24	6	
	>Rs 30,000	30.83	4.26	13.33	1.86	17.50	4.97	6	
Years of getting treatment for psychosis	1- 5 years	30.04	4.88	11.83	2.82	18.21	5.06	24	**F=2.75 P=0.05*(S)**
	6 -10 years	31.24	4.46	13.56	3.36	17.68	3.64	21	
	11- 15 years	27.30	4.69	12.80	2.74	14.50	4.79	10	
	> 15 years	29.80	2.68	15.80	2.77	14.00	2.35	5	
Side effects of antipsychotics are	Drawling of saliva	30.14	3.99	13.62	3.35	16.52	3.63	21	F=0.49 P=0.68(NS)
	Rigidity of body and neck	30.65	5.12	13.62	2.82	17.04	4.91	26	
	Eye balls moves up	29.40	4.79	13.50	2.55	15.90	4.95	10	
	Fever with palpitation	28.33	6.66	14.33	4.04	14.00	4.36	3	
EPS means	Extra psychiatric symptoms	30.19	4.05	13.04	2.52	17.15	4.25	26	F=2.57 P=0.46(NS)
	Extra pyramidal symptoms	28.95	5.05	14.14	3.45	14.81	4.18	21	
	Extra pyramidal syndrome	30.44	5.36	13.56	2.30	16.89	4.04	9	

	Extra six symptoms	29.00	5.03	15.00	4.24	14.00	4.69	4	
Treatment measure for EPS is	Getting treatment in psychiatric OPD	29.77	4.58	13.37	3.21	16.40	4.30	30	F=2.32 P=0.50(NS)
	Getting local traditional treatment	31.61	4.38	13.94	2.98	17.67	4.45	18	
	Getting black magic treatment	31.33	3.93	13.17	2.56	18.17	2.86	6	
	Stop to attending psychiatric OPD	28.50	5.47	14.50	2.17	14.00	4.00	6	

The above table 4.15 shows the association between symptom reduction knowledge score and demographic variables. Younger age caregivers,, male gender caregivers, joint family caregivers, less duration of treatment patients caregiver are having more symptom reduction knowledge than others... Statistical significance was calculated using oneway analysis of variance F-test and student independent t-test.

CHAPTER-V

DISCUSSION

The study intends to assess the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among care givers of patients on anti-psychotic drugs attending outpatient department at Institute of Mental Health , Chennai. The data was collected with the help of structured questionnaire .Paired 't' test was used to test the significant difference between pre test and post test, chi-square was used to find out the association between knowledge with selected demographic variables.

The collected data were tabulated and presented according to the objectives under the following headings

- ✓ **Section I:**

  Deals with the socio demographic variables

- ✓ **Section II:**

  Assess the pre test knowledge of caregiver regarding extra pyramidal symptoms.

- ✓ **Section III:**

  Assess the post test knowledge of caregiver regarding extra pyramidal symptoms.

- ✓ **Section IV:**

  Assess the effectiveness of psycho education module.

- ✓ **Section V:**

Association between post test knowledge score and selected demographic variables.

The first objective of the study to assess the socio demographic variables and pre test knowledge of care giver regarding extra pyramidal symptoms:

- Among 60 caregivers (63.3%) were 21-30 years, (21.7%) were 31-40 years, (10%) were 41-50 years, (5%) were 51-60 years.
- In case of sex (66.7%) were males, (33.3%) were females.
- According to living area (58.3%) were from rural, (33.4%) were from urban, (8.3%) were from semi urban.
- In marital status (60%) were married, (31.7%) were unmarried, (8.3%) were widow, and none of them in other categories.
- According to occupation status (50%) were cooly, (36.6%) were doing business, (11.7%) were state government employee, (1.7%) were central government employee.
- The type of family revealed that (51.7%) were nuclear family, (31.6%) were joint family, and (16.7%) were extended family.
- Regarding income of the family (50%) were earned Rs. 5001-10,000, (30%) were earned Rs. 10,001-20,000, (10%) Rs. 20,001-30,000, (10%) were earned more than 30,000.
- According to years of getting treatment for psychosis (40%) were 1-5 years, (35%) were 6-10 years, (16.7%) were 11-15 years and (8.3%) were more than 15 years.
- Knowledge regarding side effects of antipsychotics was (43.3%) thought rigidity of body and neck, (35%) thought drawling of

saliva, (16.7%) thought eye balls move up, (5%) thought fever with palpitation.

- Caregiver knowledge about EPS means was (43.3%) were thought extra psychiatric symptoms, (35%) were thought extra pyramidal, (15%) were extra pyramidal syndrome, (6.7%) were thought extra six symptoms.

- Caregiver knowledge about treatment measure for EPS is (50%) were thought getting treatment in psychiatric OPD, (30%) were thought getting local traditional treatment, (10%) getting black magic treatment, (10%) were thought stop to attending psychiatric OPD.

The pre test level of knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs using Glasgow Antipsychotic Side-effect Scale (GASS).

In general , none of the caregivers are having good level knowledge score, 26.7% are having Moderate level knowledge score and 73.3% of them having poor level of knowledge score on pyramidal symptoms.

The similar study conducted by Ram prasad Santhana krishna Kirgaval1*, Srinivas Revanakar[2] and Chidanand Srirangapattna (2017) Prevalence of Extra pyramidal Side Effects in Patients on Antipsychotics Drugs at a Tertiary Care Center Background: Antipsychotic drugs are associated with adverse effects that can lead to poor medication adherence, stigma, distress and impaired quality of life. Among the various side effects of anti-psychotics extra pyramidal symptoms constitute one of the important side effects interfering with the compliance of the patients towards medication. Objective: Evaluation of extra pyramidal side effects by AIMS in patients who are on antipsychotics. Results: The extra pyramidal symptoms were more commonly seen in males (62.85%), the age of incidence of maximum in the age group of (34.28%),

Maximum was seen among the patients on the Risperidone (45.7%), Involvement of the extremities was common (42.85%) and 64.28% of individuals had moderate severity and(54.28%) of individuals were aware of the extra pyramidal symptoms which provided mild distress. Conclusion: Extra pyramidal symptoms are one of the commonest side effect of the antipsychotics interfering with compliance of the patients towards adherence to medications, thereby decreasing the efficacy.

Sheela ,Ranbhise, Ashok, Kamat ,(2014) conducted a study to assess the knowledge regarding adverse effects of selected antipsychotic drugs among the caregivers of patients receiving antipsychotic drugs adopted non experimental descriptive design with descriptive survey approach was used for the present study. Non Probability sampling by using convenient sampling technique was used to select 30 samples. Data was collected by means of a Standardized Structured Knowledge Questionnaire which was divided into 2 sections which consisted socio-demographic variables and variables to assess the knowledge regarding adverse effects of anti psychotic drugs. The study findings revealed that majority of caregivers 24 (80%) had average knowledge, 5 (16.66%) had good knowledge, 1 (3.33%) had poor knowledge about adverse effects of antipsychotic drugs. There is statistically significant association found between demographic variables with knowledge score regarding adverse effects of antipsychotic drugs at the 0.05 level of significance.

The second objective of the study to determine the pre test and post test knowledge of care giver regarding extra pyramidal symptoms.

- The post test level of knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs Using Glasgow Antipsychotic Side-effect Scale (GASS).

- In general 38.3% of the caregivers are having good level knowledge score, 61.7% are having Moderate level knowledge score and none of them having poor level of knowledge score on pyramidal symptoms.

- On an average, in pre test caregivers are having 30.15score after the administration of psycho education module they are having 13.63 knowledge score. Difference is 16.51, Before education module, none of the caregivers are having good level knowledge score, 26.7% are having Moderate level knowledge score and 73.3% of them having poor level of knowledge score on pyramidal symptoms.

- After education module, 38.3% of the caregivers are having good level knowledge score, 61.7% are having Moderate level knowledge score and none of them having poor level of knowledge score on pyramidal symptoms .

- Level of knowledge score between pre test and post test was calculated using Generalised Mc Nemar's chi square test.

- On an average, in post test after having psycho education module, caregivers are having gaining knowledge score 25.03% score than pretest score.

- Differences and generalization of knowledge score between pretest and post test score was calculated using and mean difference with 95% CI and proportion with 95% CI.

- The similar study conducted by Eugenio Aguglia et al, 2007. 1, Elisabetta Pascolo-Fabrici 1, Francesca Bertossi1 and Mariano Bassi Eugenio Aguglia*

A synergy of drug therapy and psychosocial interventions can give more benefits in treatment .Methods: A perspective study was conducted on 150 patients with schizophrenia over 15 centers in Italy. The experimental group was treated with drug therapy, traditional psychosocial and psycho education for the patients and their families, while the control group received traditional psychosocial and drug intervention over 1 year. Results: The experimental group showed a significant statistical improvement ($p < 0,05$) in almost all the scales that have been assessed (BPRS, SAPS, SANS, SIMPSON-ANGUS SCALE,

LANCASHIRE QL SCALE). Significant was the reduction of the number of hospitalizations and of days of hospital stay .Conclusion: As it is shown in international literature, psycho educational intervention with schizophrenic patients and their families can reduce the occurrence of relapse.

The third objective of the study to find association between post test knowledge score and selected demographic variables.

The association between pre test level of symptom knowledge and their demographic variables.

None of the demographic variables are significantly associated with their pre test level of knowledge score. Statistical significance was calculated using chi square test.

The association between post test level of knowledge and caregivers demographic variables.

Younger age caregivers, male gender caregivers, joint family caregivers, less duration of treatment patients caregiver are having more symptom

reduction knowledge than others..Statistical significance was calculated using chi square test. The similar study conducted by Sayali Devidas Dambhe, Muniyand i S.Effectiveness of Planned Teaching about Knowledge Regarding side Effects of Typical Antipsychotics among the Primary care givers of Psychiatric Patient in selected Hospital. Asian J. Nursing Education and Research. 2018; 8(1): 81-93.

Objective: Assess the level of knowledge regarding side effects of typical antipsychotics among primary care givers of psychiatric patients. To assess the effectiveness of planned teaching on knowledge regarding typical antipsychotics among primary care givers of psychiatric patients. To find out the association between level of knowledge among primary care givers of mentally ill client with their selected demographic variables.

Research approach: Present study was conducted on quantitative approach is used in this study. This approach was selected because the aim of this research study was to evaluate the effectiveness of planned teaching in improving the knowledge of primary care giver regarding side effects of typical antipsychotics drugs. With this approach it would be possible to describe the knowledge of primary care givers regarding side effects of typical antipsychotic drug. The quantitative approach would help the investigator to evaluate the effect of "Planned teaching" on the variable that is knowledge of the primary care givers.

Research Design: One group pre-test post-test design has been used to fine the effectiveness of planned teaching about knowledge regarding side effects of typical antipsychotics among the primary care givers of psychiatric patient in selected hospital and also to determine the association between knowledge of primary care givers regarding side effect of typical antipsychotics with their selected demographic variables. A pre test was administered on day 1 by means of structural questionnaire depicted as Q1 and then planned teaching also conducted on day 1 depicted as X. A post test was conducted on day 7 using

the same structured questionnaire depicted as Q2. The study design depicted as (Q1,X ,Q2).

Setting of the study: The study was conducted in a selected hospital. The rationale for selecting this setting was easy transport, familiarity with the setting, administrative approval, cooperation and availability of subject. Sample and sampling technique: In this study sample size was 40 primary care giver of psychiatric patient who take typical antipsychotics. Sampling refers to the process of selecting the portion of the population to represent the entire population.

Tool: Knowledge questionnaire is used to gather information.

Validity and reliability: Reliability of the tool is a major criterion for assessing the quality and accuracy. It is the degree of consistency with which it measures the attribute. Reliability analysis was done by KR20 formula. The reliability coefficient correlation for structured knowledge questionnaire was 0.70 To obtain content validity of the tool, the prepared tool with synopsis, planned on side effects of typical antipsychotics, evaluator's response sheet and content validity certificate were submit to 14 experts in the field of psychiatric nursing and psychiatry. All validated contents of the tools were received back from the experts with their valuable suggestion and comments.

Pilot study: The investigator conducted the pilot study in selected hospital from 23th December 2016 to 30th December 2016. For the present study, the investigator obtained formal approval from the medical superintendent of in selected hospital. The investigator selected 4 samples by non-probability convenient sampling technique. After a brief self-introduction, the investigator explained the purpose of the study and obtained consent from them. Good rapport was established. The investigator conducted the pre-test and doubts were clarified. After that, planned teaching was given to the primary Finding of the study: The finding including of the study includes, the analysis and interpretation of data collected from the primary care givers in selected

hospital. Among the total 40 sample of primary care givers out of 14(35%)in 29-38 years of age ,most of samples were female 24(60%),12(50%) having secondary education, 26(65%)of subjects belonged to Hindu religion,21(52.5%) of sample was on private job, 22(55%) sample having upto10000, 22(55%) samples was from to urban area 26(65%) were having length of stay of more than 2 year. The frequency and percentage distribution of level of knowledge among primary care givers in pre-test. Among 40 samples the pre test score 3(7.5%) subjects were having poor knowledge (0-6) regarding the side effects antipsychotics, while 29(72.5%) had average knowledge (7-12),whereas 8(20%)subject had good knowledge (13-18)and none of the subjects had excellent knowledge about it. While in the post - test,1(2.5%) of the subject had average knowledge,19(47.5%)subject had good knowledge and 20(50%)subject had excellent knowledge regarding the side effects of antipsychotics. The comparison between the mean difference in pre-test and post test score was 8.2. The calculated‘t ' value was 13.71, whereas the tabulated‘t’ value was 2.02, shows that the calculate ‘t’ value was much higher than the tabulated 't' value. It shows that the planned teaching was effective in significant improving the knowledge of primary care givers of psychiatric patient regarding side effects of typical anti psychotics, so the null hypothesis H0 is rejected and the research hypothesis H1 is accepted.

Conclusion: The analysis of the study revealed that there was a significant improvement in the knowledge of primary care givers. The planned teaching proved to be effective in improving the knowledge and attitude of the primary care givers of psychiatric patient in selected hospital.

CHAPTER VI

SUMMARY, RECOMMENDATION AND NURSING IMPLICATION OF THE STUDY

6.1 SUMMARY OF THE STUDY

The main focus of the study was to assess the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs. Antipsychotics induced extra pyramidal symptoms include a variety of movement disorders. Acute extra pyramidal symptoms are like acute dystonia, akathisia and Parkinsonism develop within hours or weeks after initiating or increasing doses of antipsychotics. Tardive dyskinesia and tardive dystonia are delayed onset syndromes and usually develop after a prolonged use of anti psychotics.

Descriptive and inferential statistics was used for comparison and association of pre-test and post test values of psycho education module. Association was found by using chi-square test. The association between pre test level of symptom knowledge and their demographic variables.

None of the demographic variables are significantly associated with their pre test level of knowledge score. Statistical significance was calculated using chi square test.

The association between post test level of knowledge and caregivers demographic variables.

Younger age caregivers, male gender caregivers, joint family caregivers, less duration of treatment patients caregiver are having more symptom reduction knowledge than others..Statistical significance was calculated using chi square test.

The paired ‘t’ test was used to analyse the effectiveness of psycho education module on knowledge of extra pyramidal symptoms among caregivers of the patients taking anti psychotics. It was found that ‘t’ value was statistically significant at 5% level. This shows that psycho education module was effective.

So the researcher conducted a study to assess the effectiveness of psycho education module to improve the knowledge of care givers of patients taking anti psychotics in Institute of mental health at Chennai. The data was collected for 4 weeks in Institute Mental Health, Chennai, from 02.01.2018 to 29.01.2018.

MAJOR FINDINGS OF THE STUDY

6.1.1. Findings of socio demographic profile of the care givers of patients with anti psychotics.

- Among 60 caregivers (63.3%) were 21-30 years, (21.7%) were 31-40 years, (10%) were 41-50 years, (5%) were 51-60 years.
- In case of sex (66.7%) were males, (33.3%) were females.
- According to living area (58.3%) were from rural, (33.4%) were from urban, (8.3%) were from semi urban.
- In marital status (60%) were married, (31.7%) were unmarried, (8.3%) were widow, and none of them in other categories.
- According to occupation status (50%) were cooly, (36.6%) were doing business, (11.7%) were state government employee, (1.7%) were central government employee.
- The type of family revealed that (51.7%) were nuclear family, (31.6%) were joint family, and (16.7%) were extended family.

- Regarding income of the family (50%) were earned Rs. 5001-10,000, (30%) were earned Rs. 10,001-20,000, (10%) Rs. 20,001-30,000, (10%) were earned more than 30,000.

- According to years of getting treatment for psychosis (40%) were 1-5 years, (35%) were 6-10 years, (16.7%) were 11-15 years and (8.3%) were more than 15 years.

- Knowledge regarding side effects of antipsychotics was (43.3%) thought rigidity of body and neck, (35%) thought drawling of saliva, (16.7%) thought eye balls moves up, (5%) thought fever with palpitation.

- Caregiver knowledge about EPS means was (43.3%) were thought extra psychiatric symptoms, (35%) were thought extra pyramidal, (15%) were extra pyramidal syndrome, (6.7%) were thought extra six symptoms.

- Caregiver knowledge about treatment measure for EPS is (50%) were thought getting treatment in psychiatric OPD, (30%) were thought getting local traditional treatment, (10%) getting black magic treatment, (10%) were thought stop to attending psychiatric OPD.

6.1.2 Finding the pre test level of knowledge of extra pyramidal symptoms among caregivers of patients on antipsychotic drugs.

In general, none of the caregivers are having good level knowledge score, 26.7% are having Moderate level knowledge score and 73.3% of them having poor level of knowledge score on pyramidal symptoms.

6.1.3. Finding the post test level of knowledge of extra pyramidal symptoms among caregivers of patients on antipsychotic drugs

The post test level of knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs Using Glasgow Antipsychotic Side-effect Scale (GASS).

In general 38.3% of the caregivers are having good level knowledge score, 61.7% are having Moderate level knowledge score and none of them having poor level of knowledge score on extra pyramidal symptoms.

6.1.4 Finding the effectiveness of psycho education module on knowledge regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs

On an average, in pre test caregivers are having 30.15score after the administration of psycho education module they are having 13.63 knowledge score .Difference is 16.51, This difference is statistically significant. Statistical significance was calculated by using student's paired 't'test.

Differences and generalization of knowledge score between pretest and posttest score was calculated using and mean difference with 95% CI and proportion with 95% CI.

In this study effectiveness of the study is point estimate of 25.03% and interval estimate is 23.28% to 26.75%. It means in this similar setup of the study, whom ever conducted , 95 % we can assure , effectiveness of the study will lies between 23.28% to 26.75%symptom knowledge score.

6. 1.5. Finding of an association of knowledge of care givers with the selected demographic variables

Younger age caregivers, male gender caregivers, joint family caregivers, less duration of treatment patients caregiver are having more symptom reduction knowledge than others..Statistical significance was calculated using chi square test.

6.2 NURSING IMPLICATIONS OF THE STUDY

The finding of the study has implications for nursing education, nursing practice, nursing research and nursing administration.

6.2.1.NURSING PRACTICE

- Survey can be conducted to identify the risk group within the community.
- Screening camps can be arranged and early detection can be done treat and prevent EPS
- The psychiatric nurse must have knowledge in teaching EPS and prevention methods in various aspects.
- The psychiatric nurse can teach the other staff nurses and the nursing students regarding EPS

6.2.2. NURSING EDUCATION

- Conferences, workshops and seminars can be held for nurses to impart update the Knowledge and positive attitudes towards antipsychotic drugs management.
- In – service education to update their knowledge and skills in various health care settings should be given.
- Nursing curriculum has to focus on enabling the nursing students to develop skill in identifying risk groups and prevents the side effect.

6.2.3. NURSING ADMINISTRATION

- The present study is proposed to help the administrators to strategically plan and meet the health needs of the patients taking anti psychotics.

- The administrators in both private and government sectors should take initiative actions to update the knowledge of risk groups on schizophrenia.

- The administrator can encourage the nurses for conducting research in various aspects of psychotrophic medications and its importance.

- The administrator can organize conference, workshop and seminars for nurses working in the psychiatric hospital.

- The administrator should support the staffs to conduct programmes regarding promoting knowledge of extra pyramidal symptoms.

6.2.4. NURSING RESEARCH

- The study will be valuable reference material for further researchers.
- This study is a preliminary set up for exploring the concepts of knowledge of side
- effects of antipsychotics
- The results of the study encourage the care givers of patients taking anti psychotics to adopt healthy life styles.

6.3. RECOMMENDATIONS

The study recommends the following for future research;

- A similar study can be undertaken for a large sample in different settings.
- A comparative study can be conducted among the staff nurses within the organisation.
- A similar study can be conducted among caregivers at different settings.
- A similar study to be conducted among nursing students.

6.4 LIMITATION OF THE STUDY

- The study was limited to the care givers of patients on anti psychotics.
- The study was limited to the selected hospital at Chennai.
- The care givers who were to participate in the study.
- The data collection was restricted only for 4 weeks.
- The knowledge level was assessed based on the score obtained.

6.5. CONCLUSION

Education in evidence based care gives the opportunity to nurses to improve their ability to use theoretical knowledge in practice. So the nurses should educate the care givers to understand the side effects of extra pyramidal symptoms and advantages of psycho education .This chapter enlightens the importance of this research and reveals that the gaining of knowledge among care givers of patients on anti psychotics.

FIG.2.2.1 MODIFIED ORLANDO THEORY OF NURSING

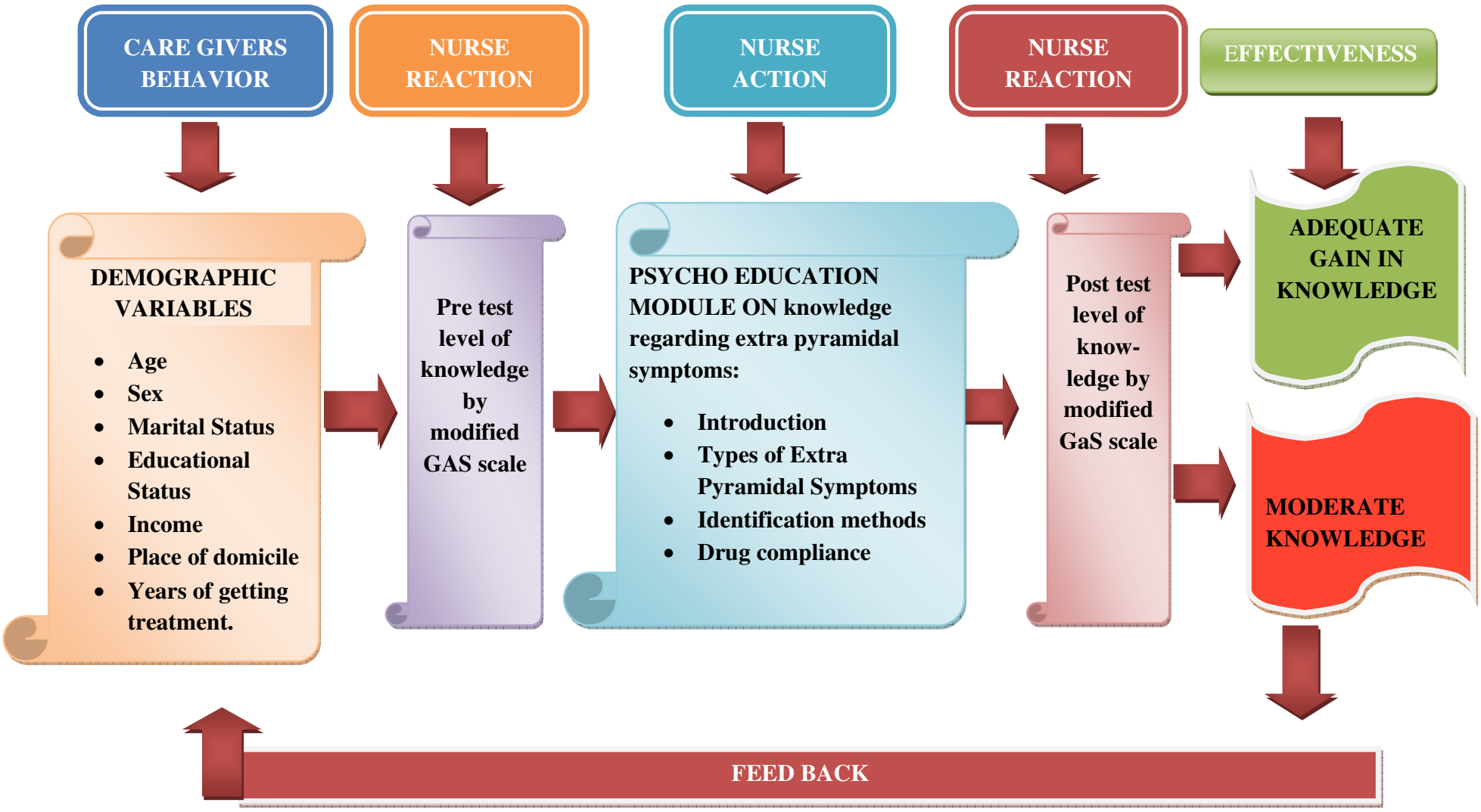
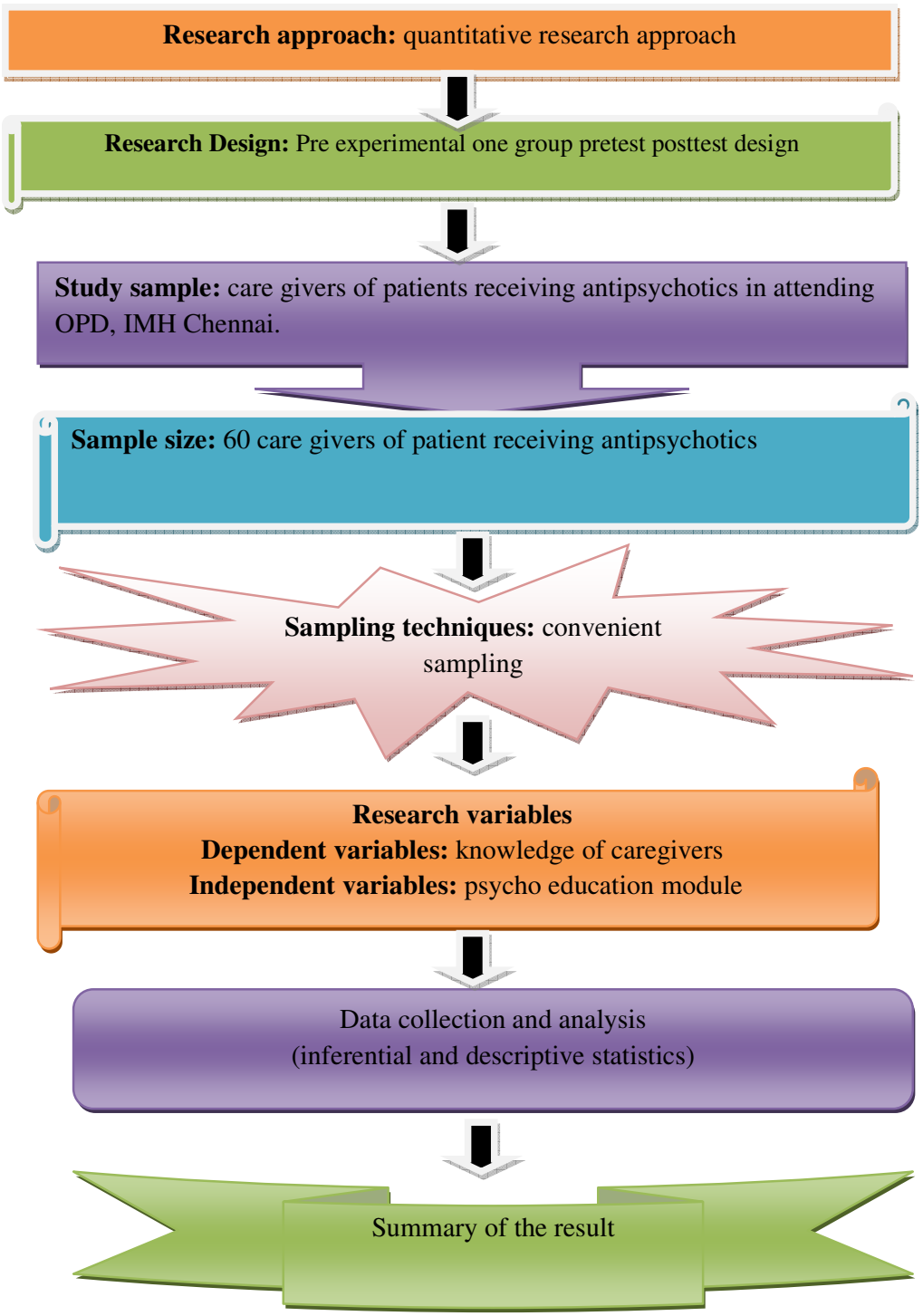


FIG.3.1 SCHEMATIC PRESENTATION OF RESEARCH MTHODOLOGY



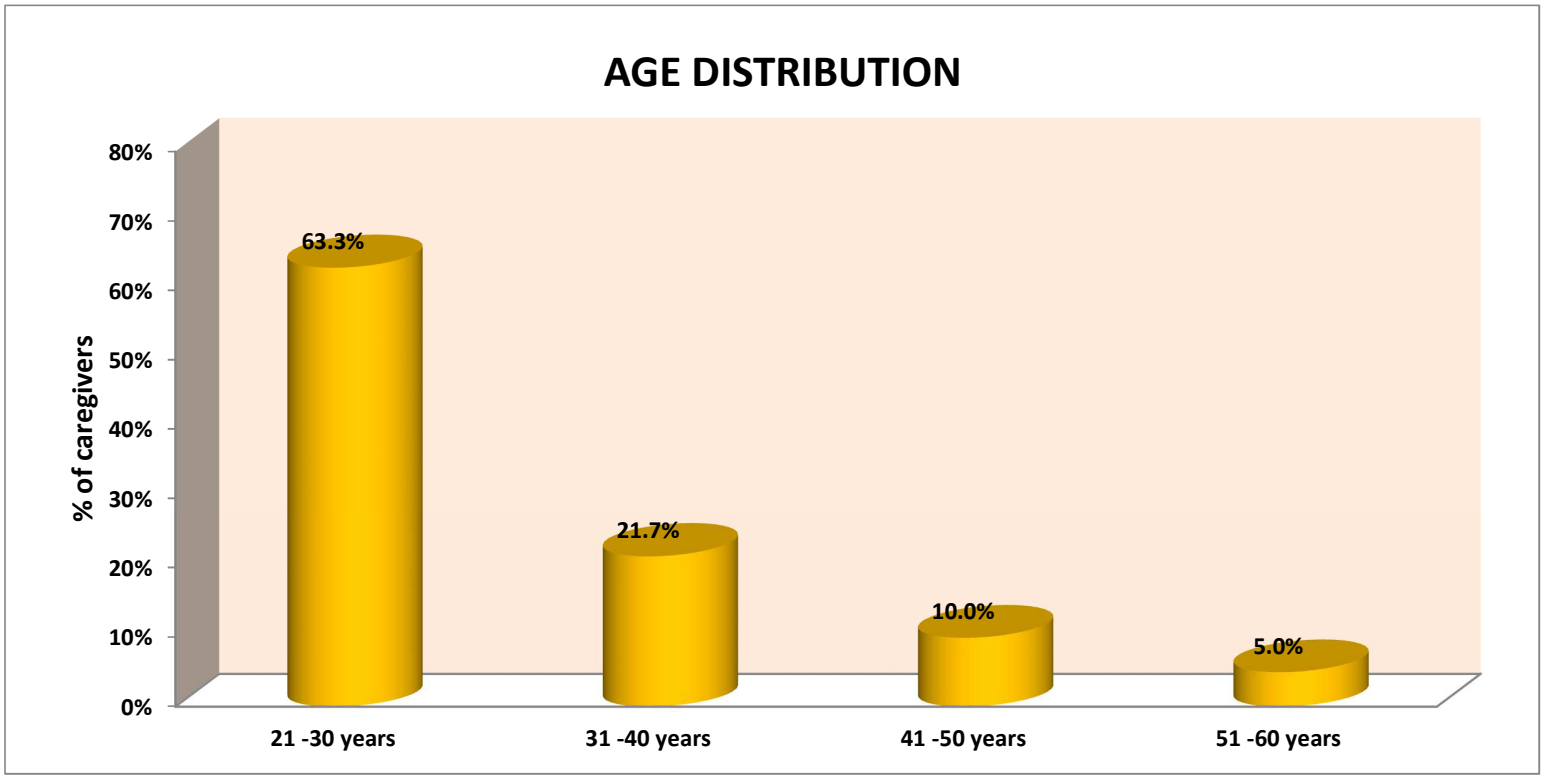


Fig 4.1 Age distribution of caregivers

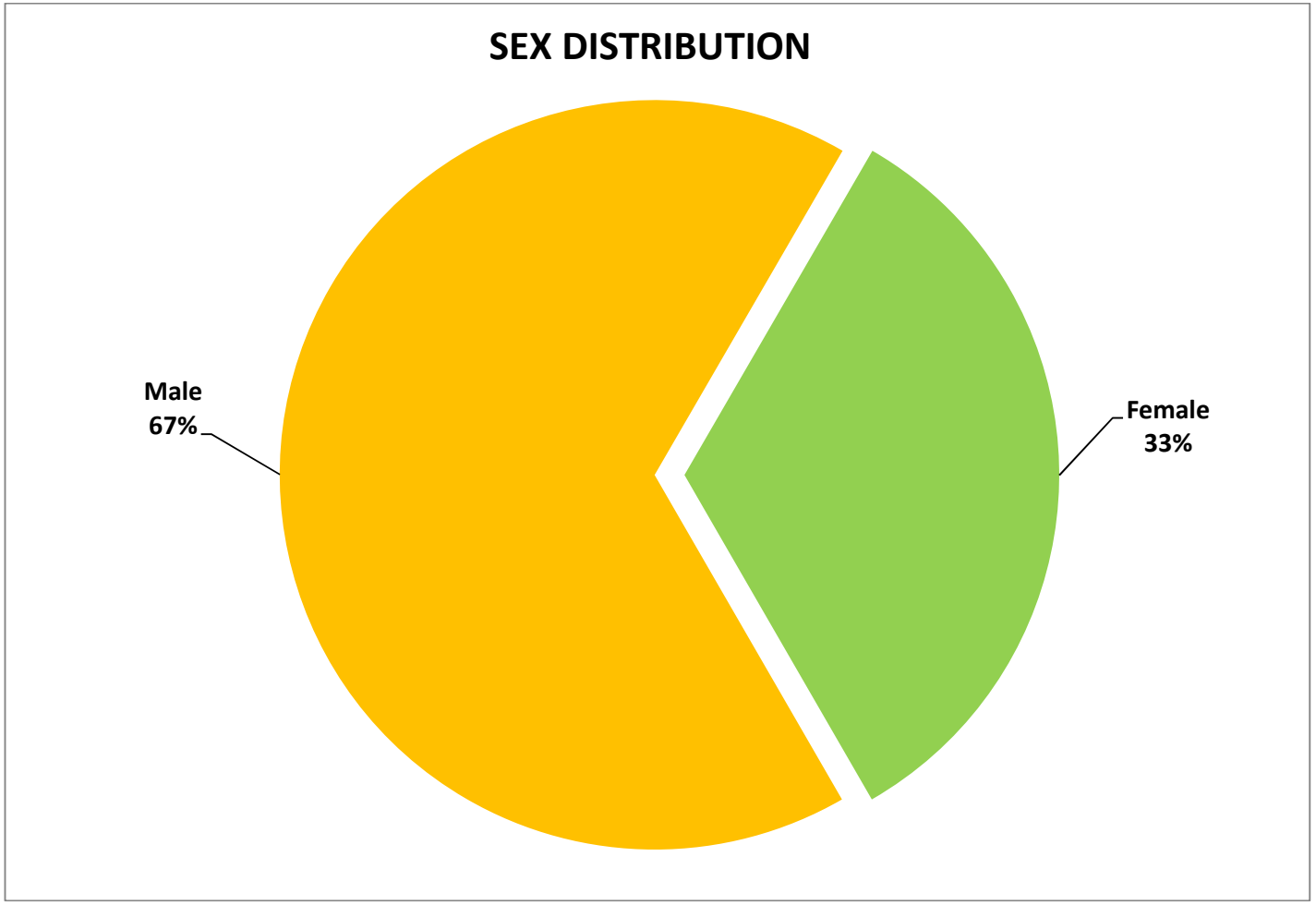


Fig 4.2 Sex distribution of caregivers

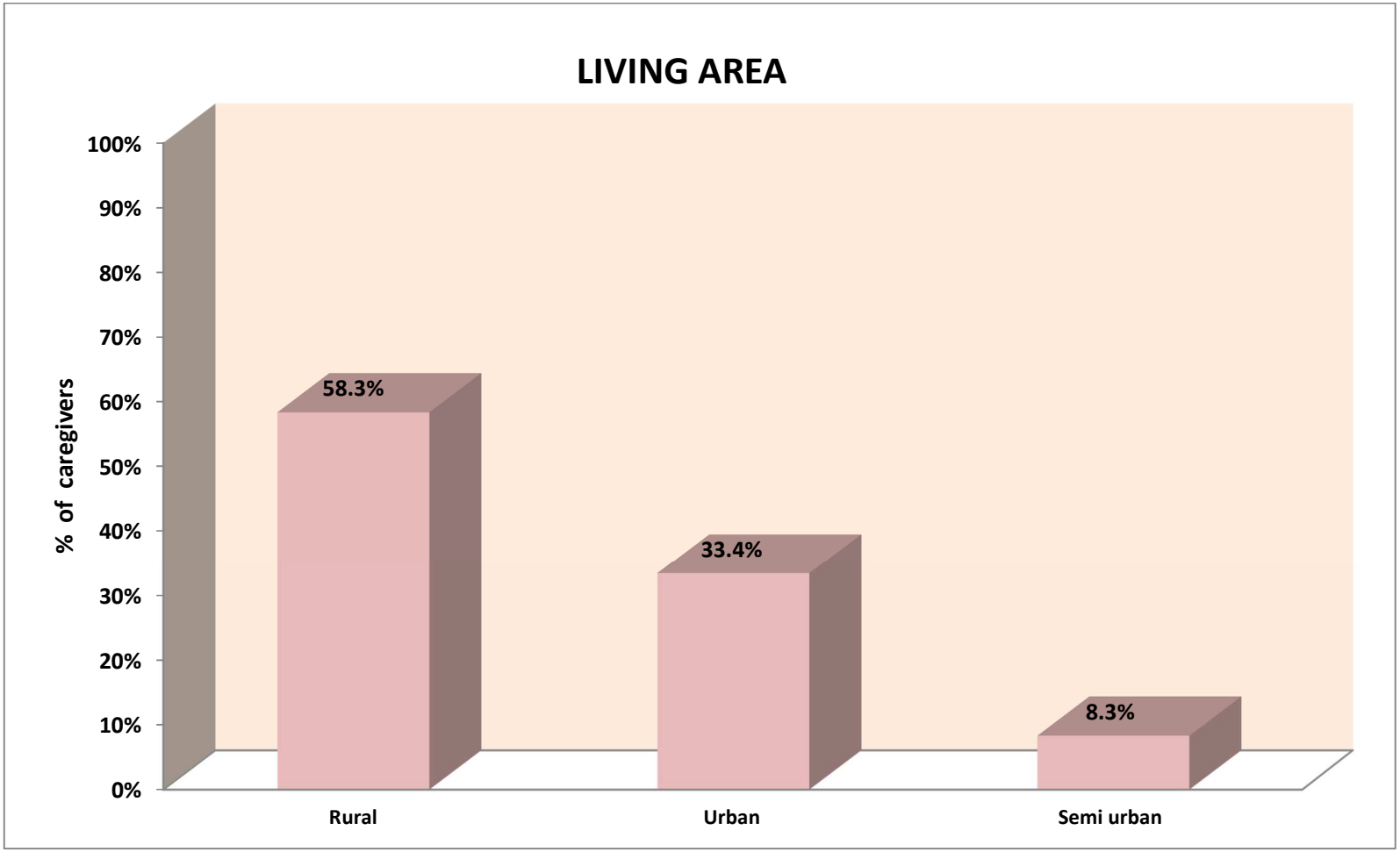


Fig 4.3 Living area of caregivers

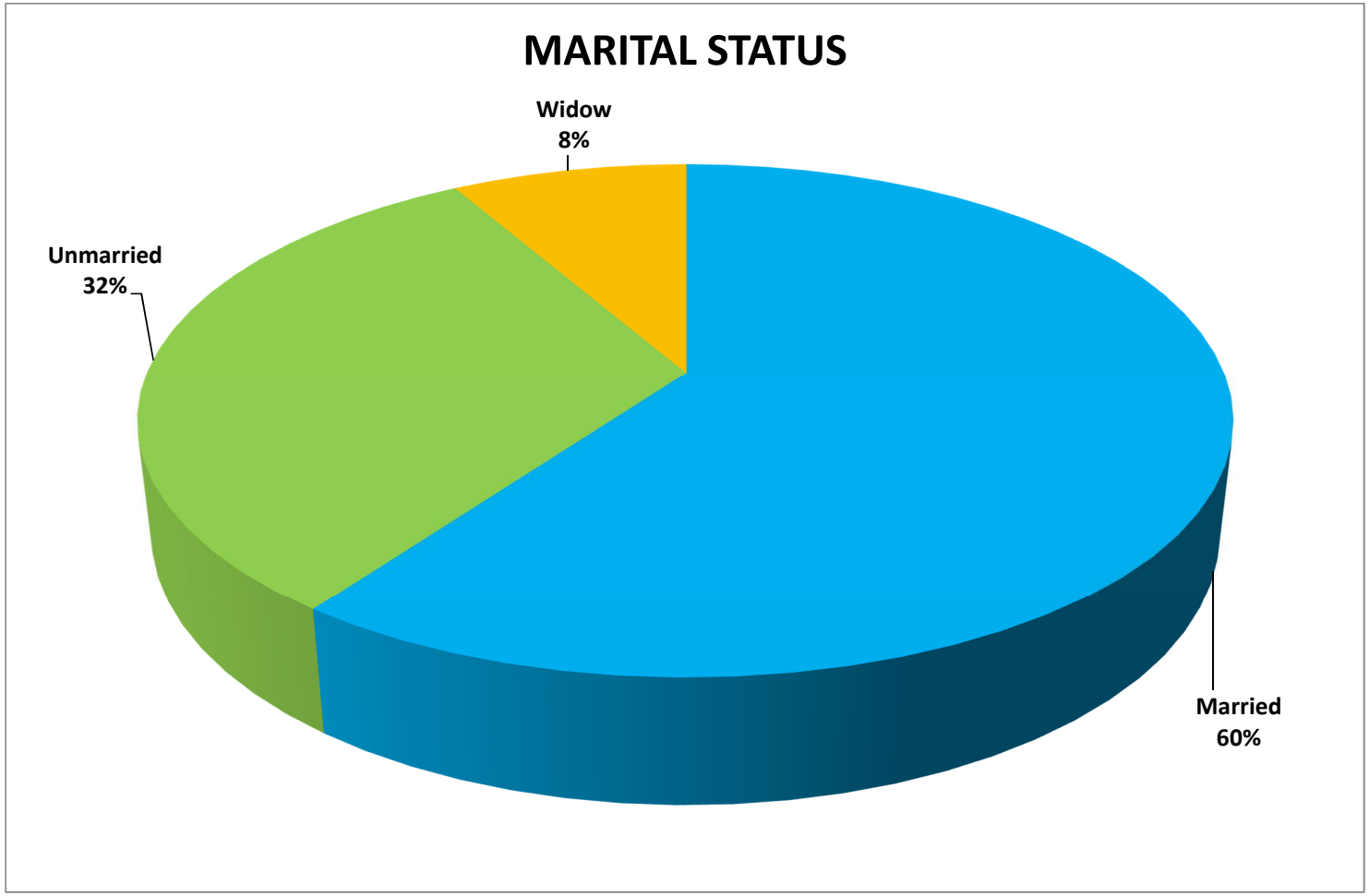


Fig 4.4 Marital status of caregivers

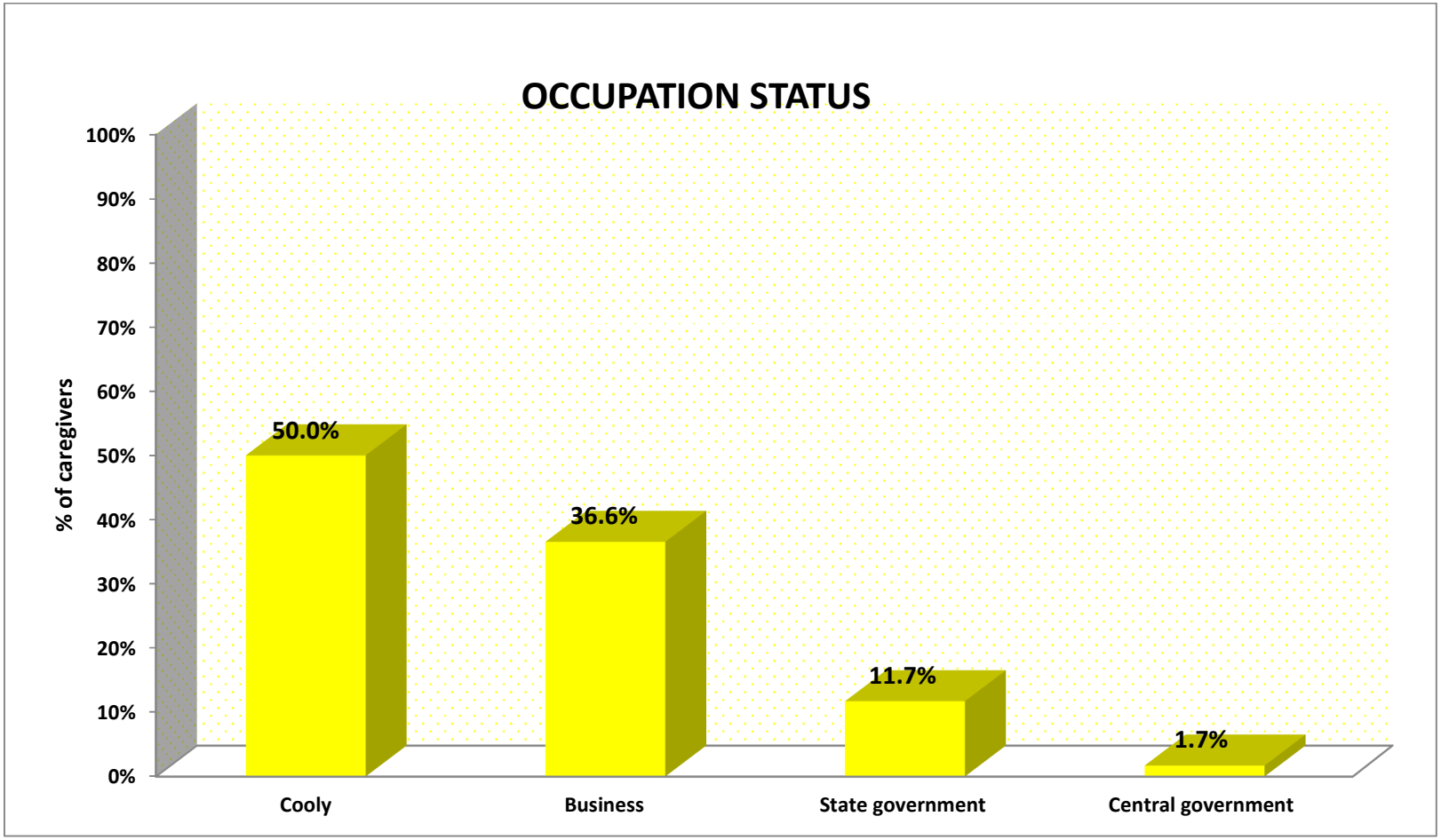


Fig 4.5 occupational status of caregivers

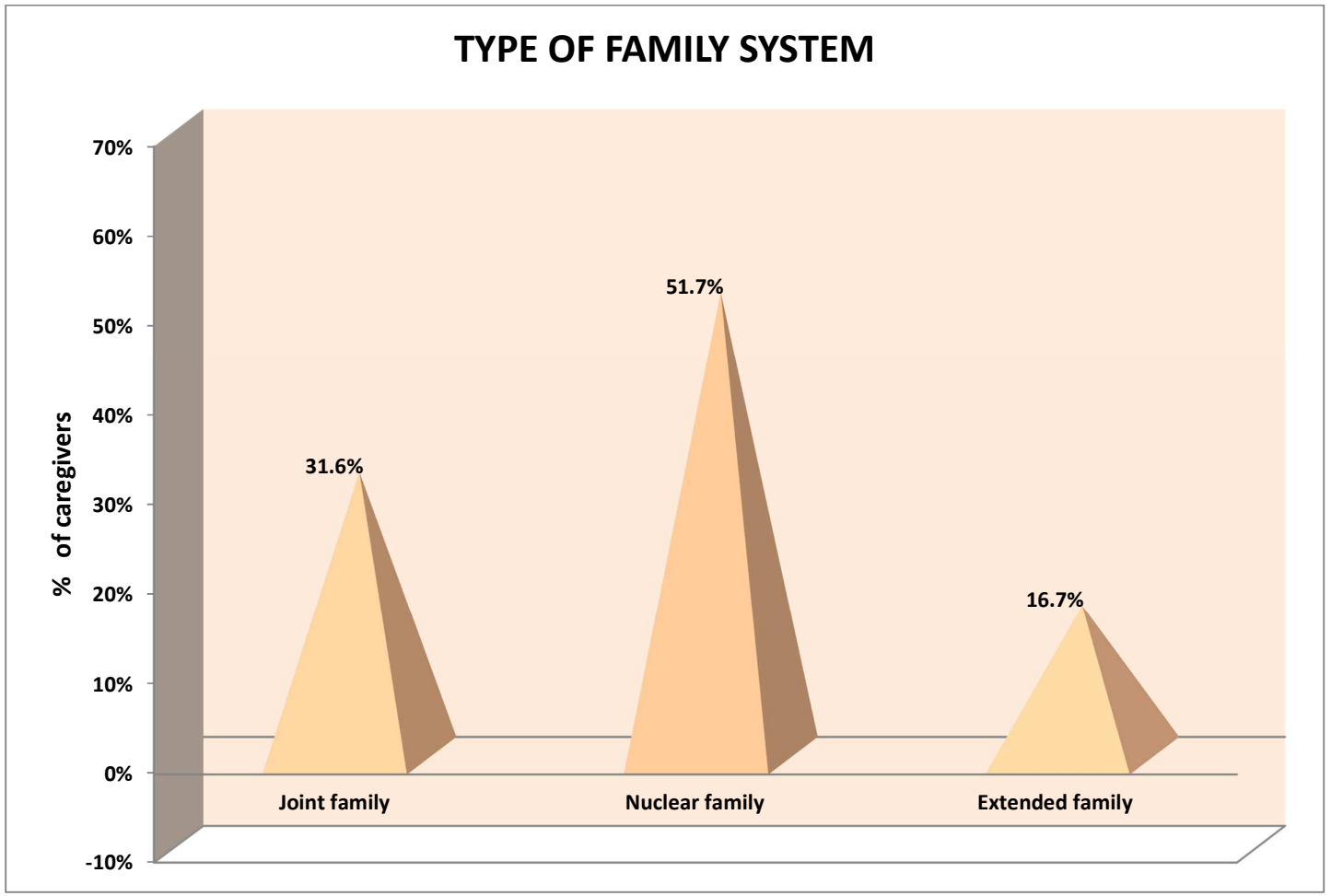


Fig 4.6 Type of family system of caregivers

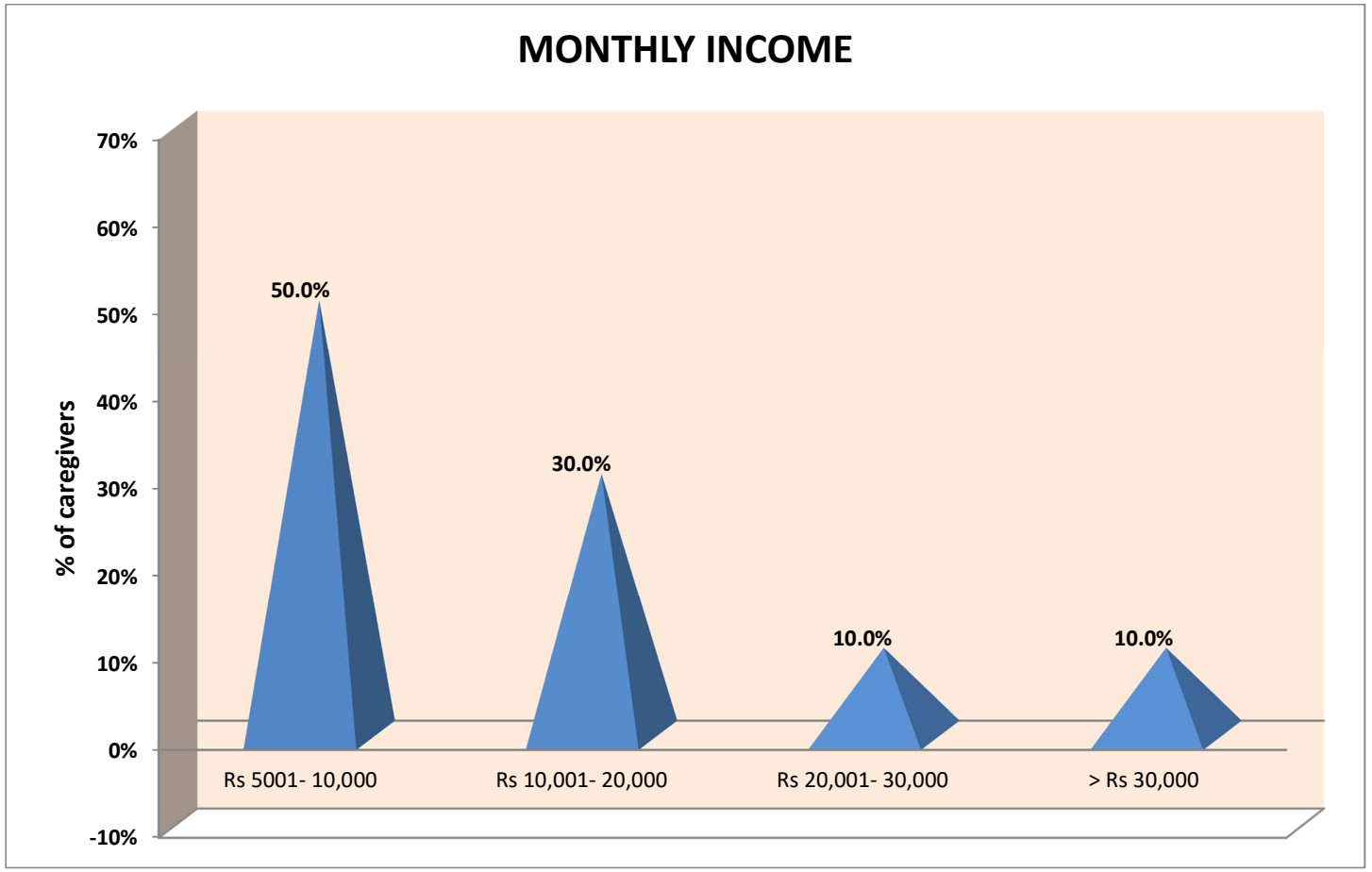


Fig 4.7 Monthly income of caregivers

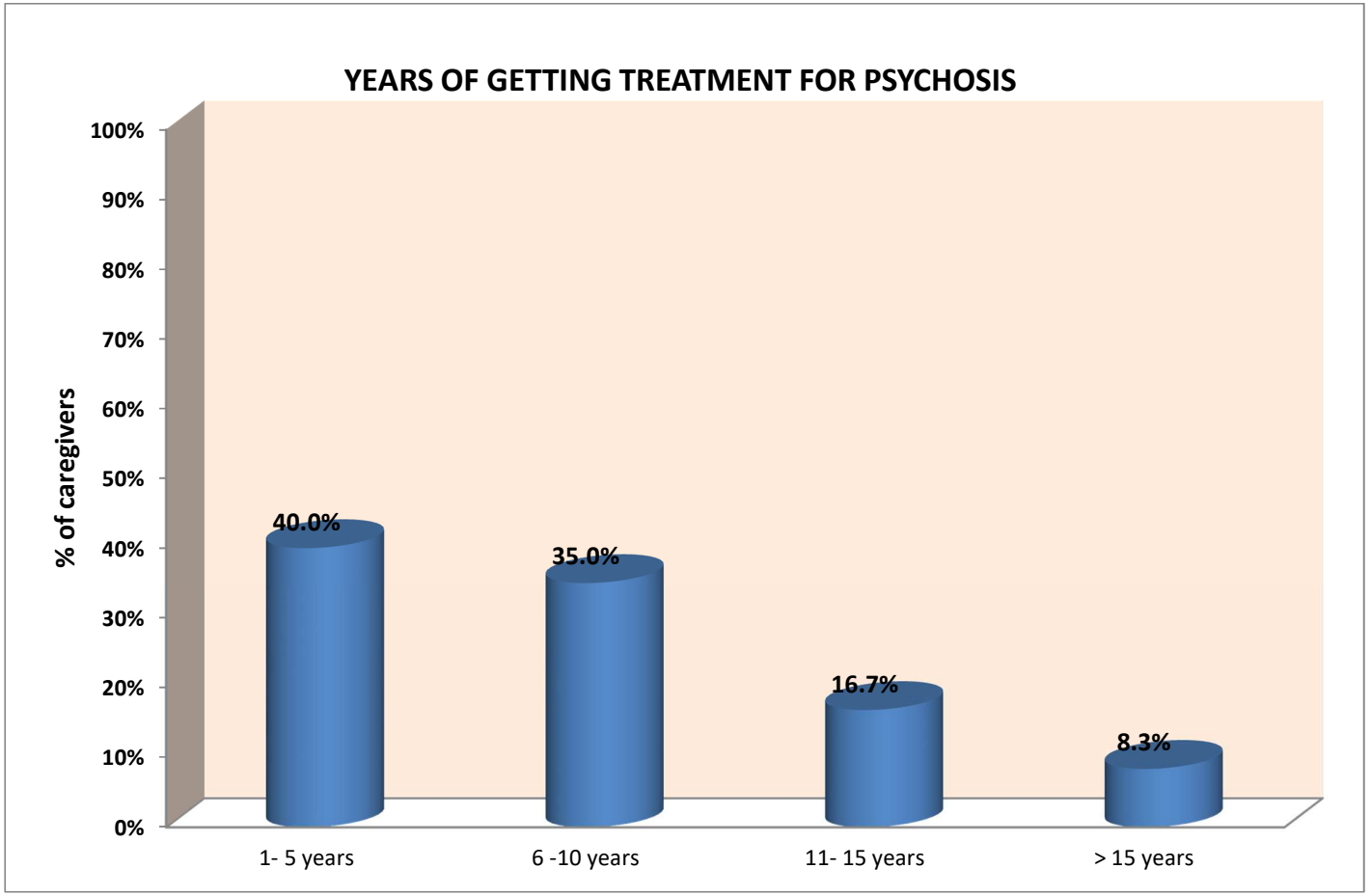


Fig 4.8 Years of getting treatment for psychosis

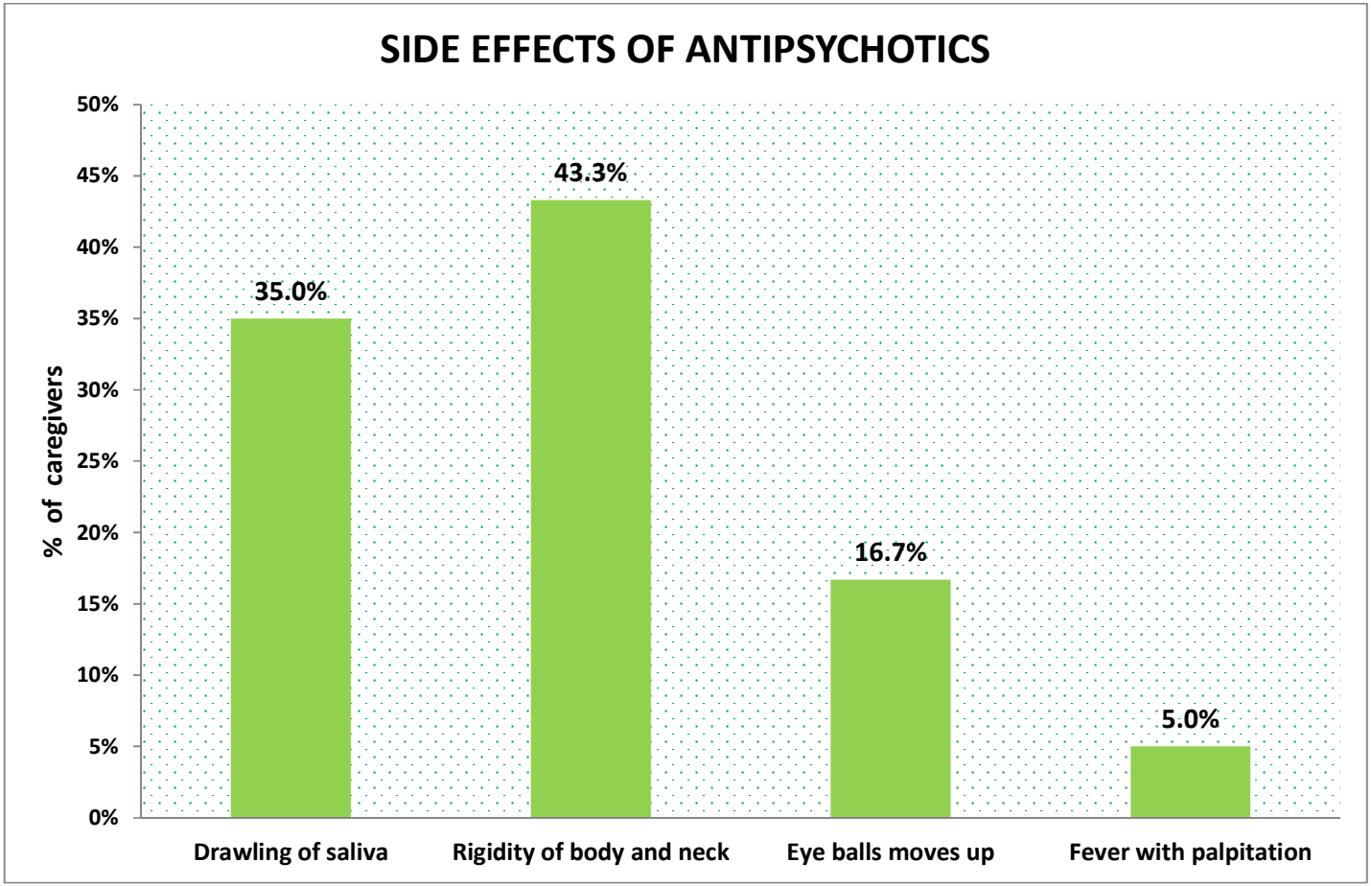


Fig 4.9 Knowledge regarding side effects of antipsychotics

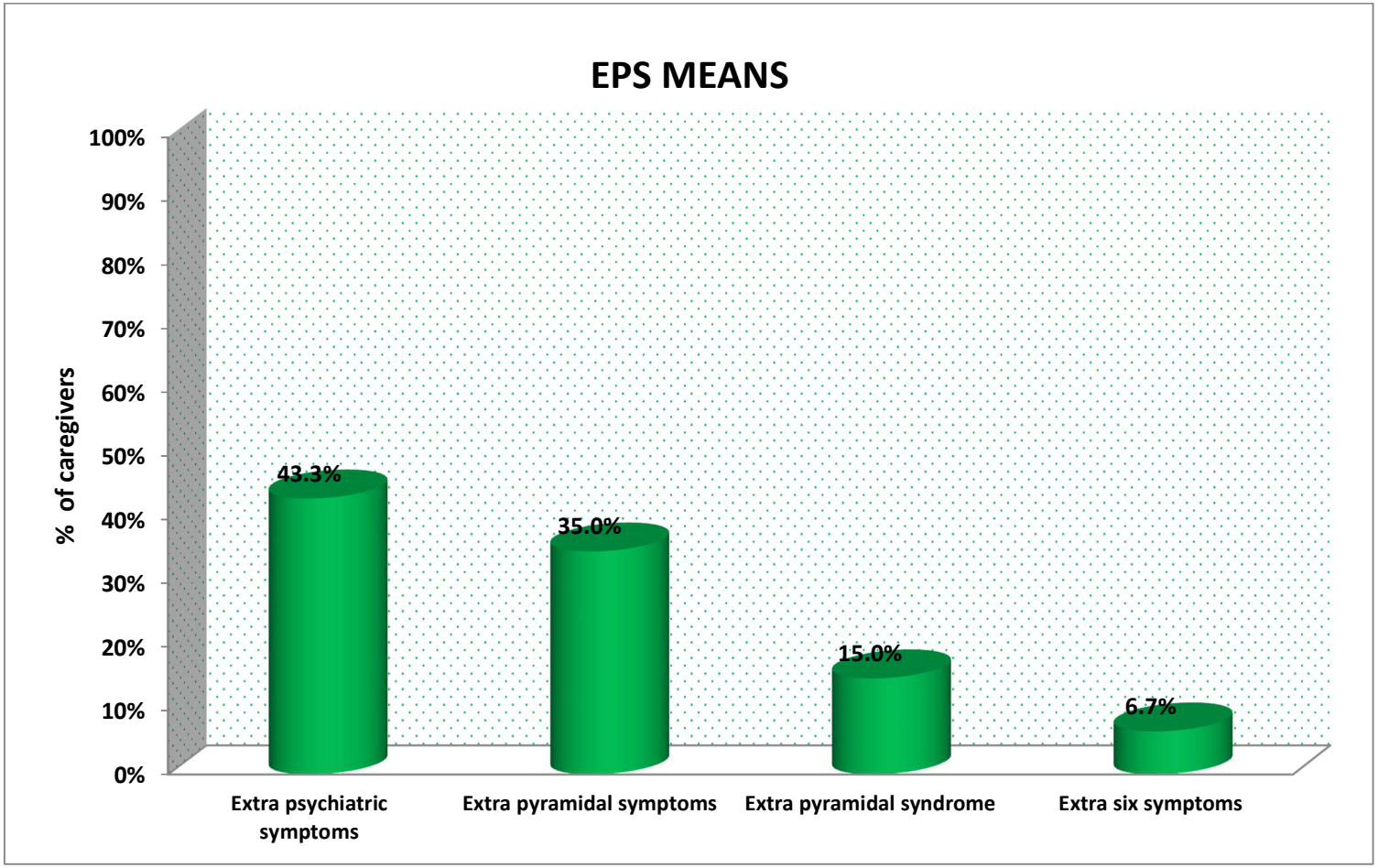


Fig 4.10 Knowledge regarding EPS means

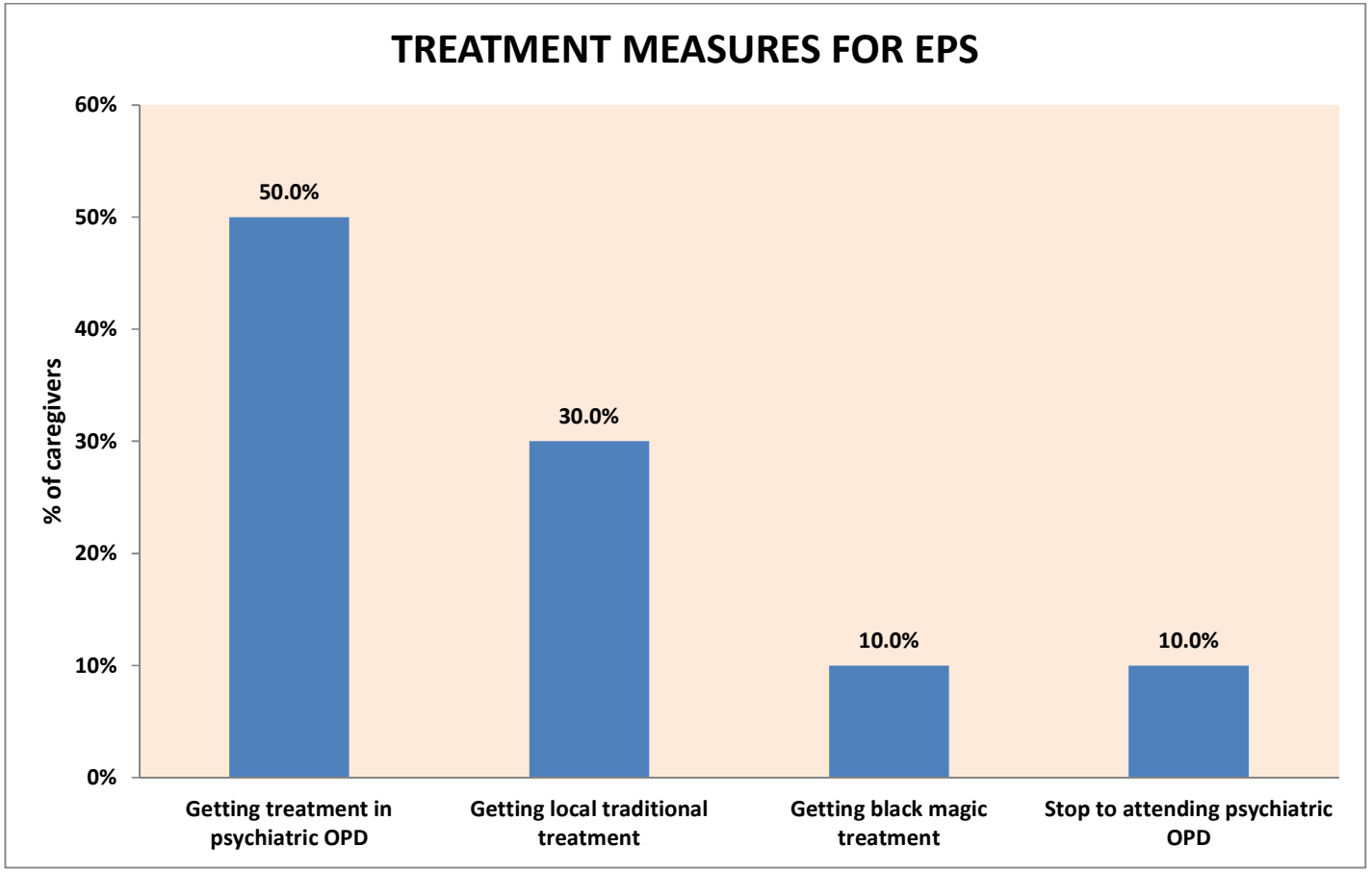


Fig 4.11 Treatment measures for EPS

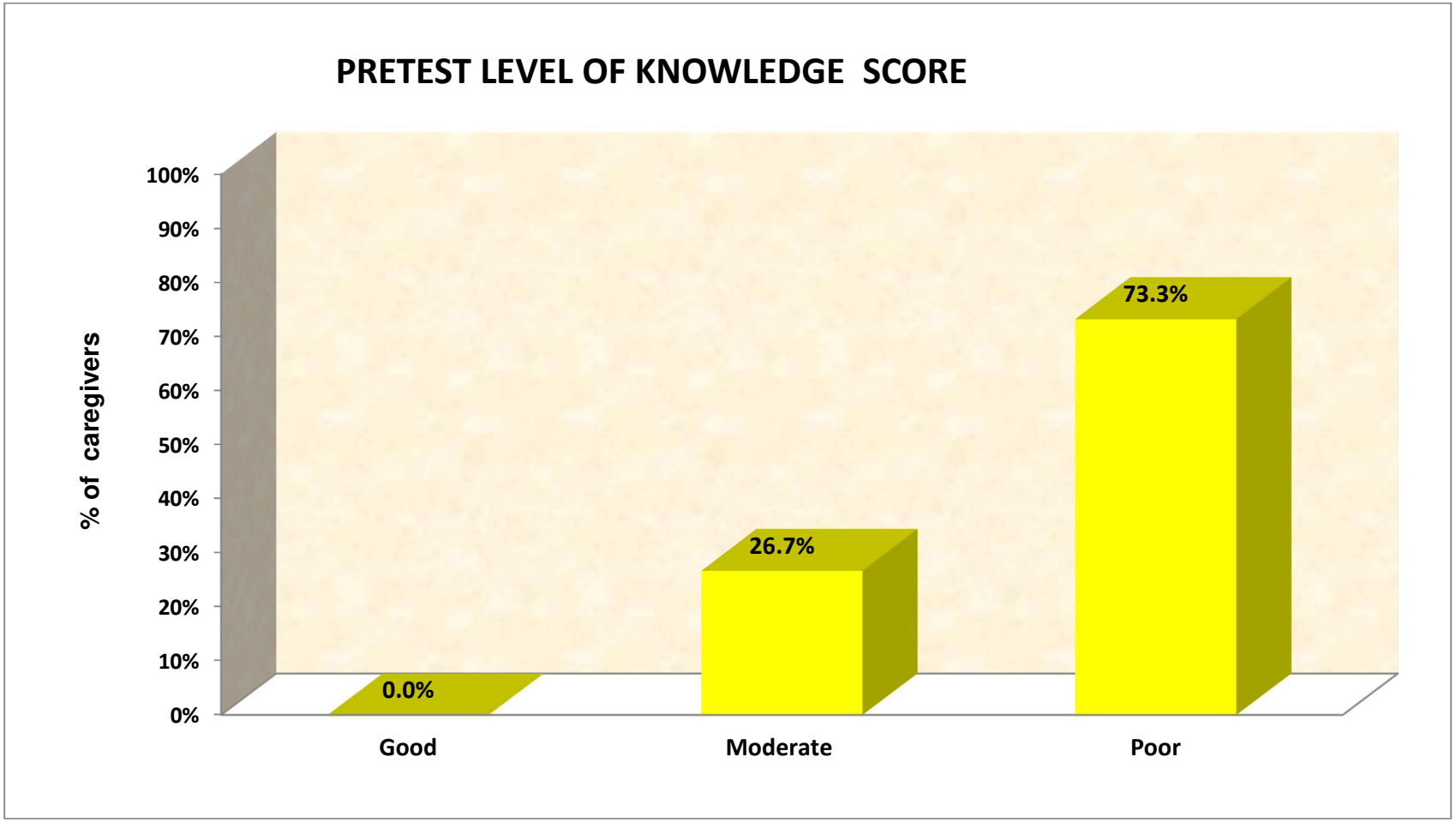


Fig 4.12 pretest level of knowledge score among caregivers

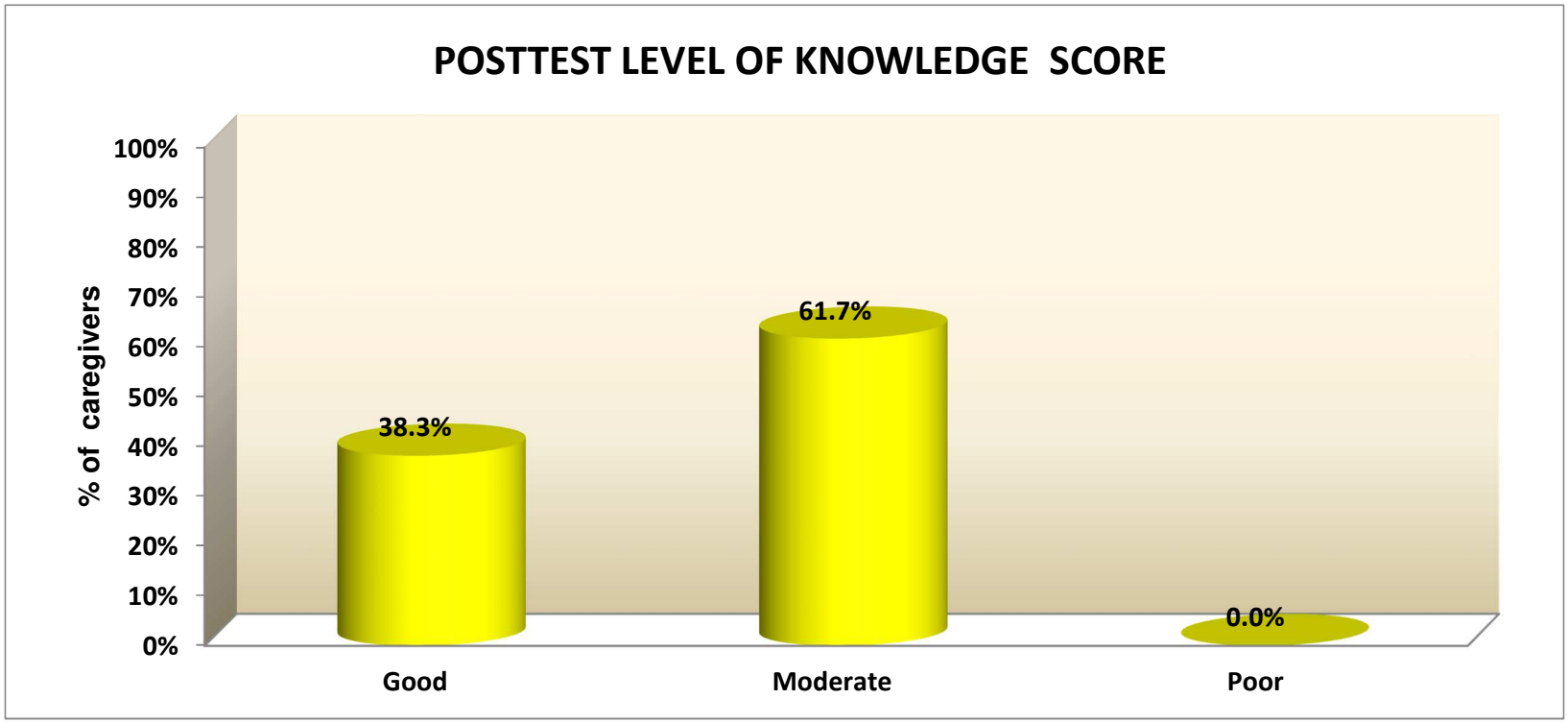


Fig 4.13 Post test level of knowledge score of caregivers

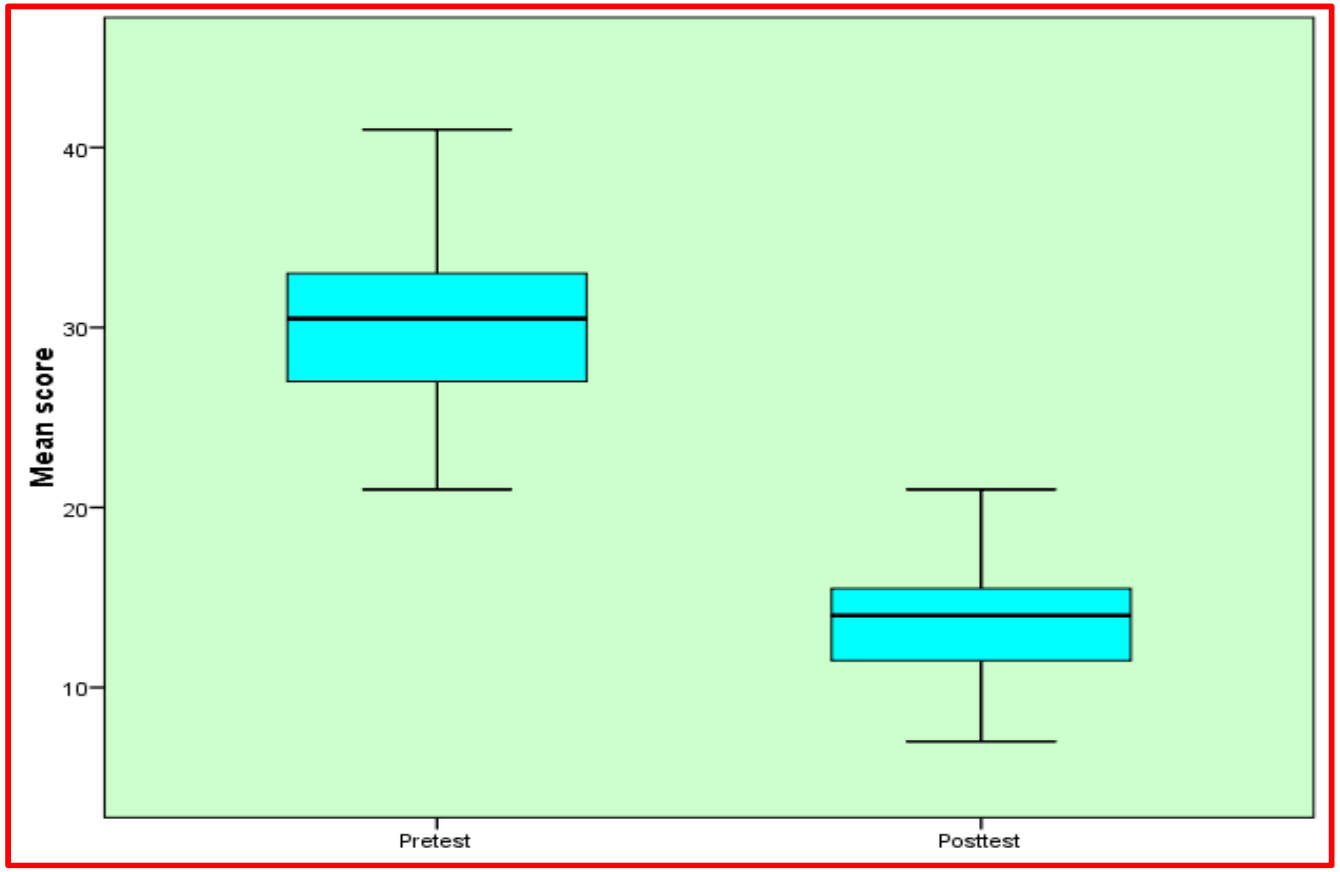


Fig 14: Box Plot Compares the caregivers pretest and posttest knowledge score regarding extra pyramidal symptoms among caregivers of patients on antipsychotic drugs.

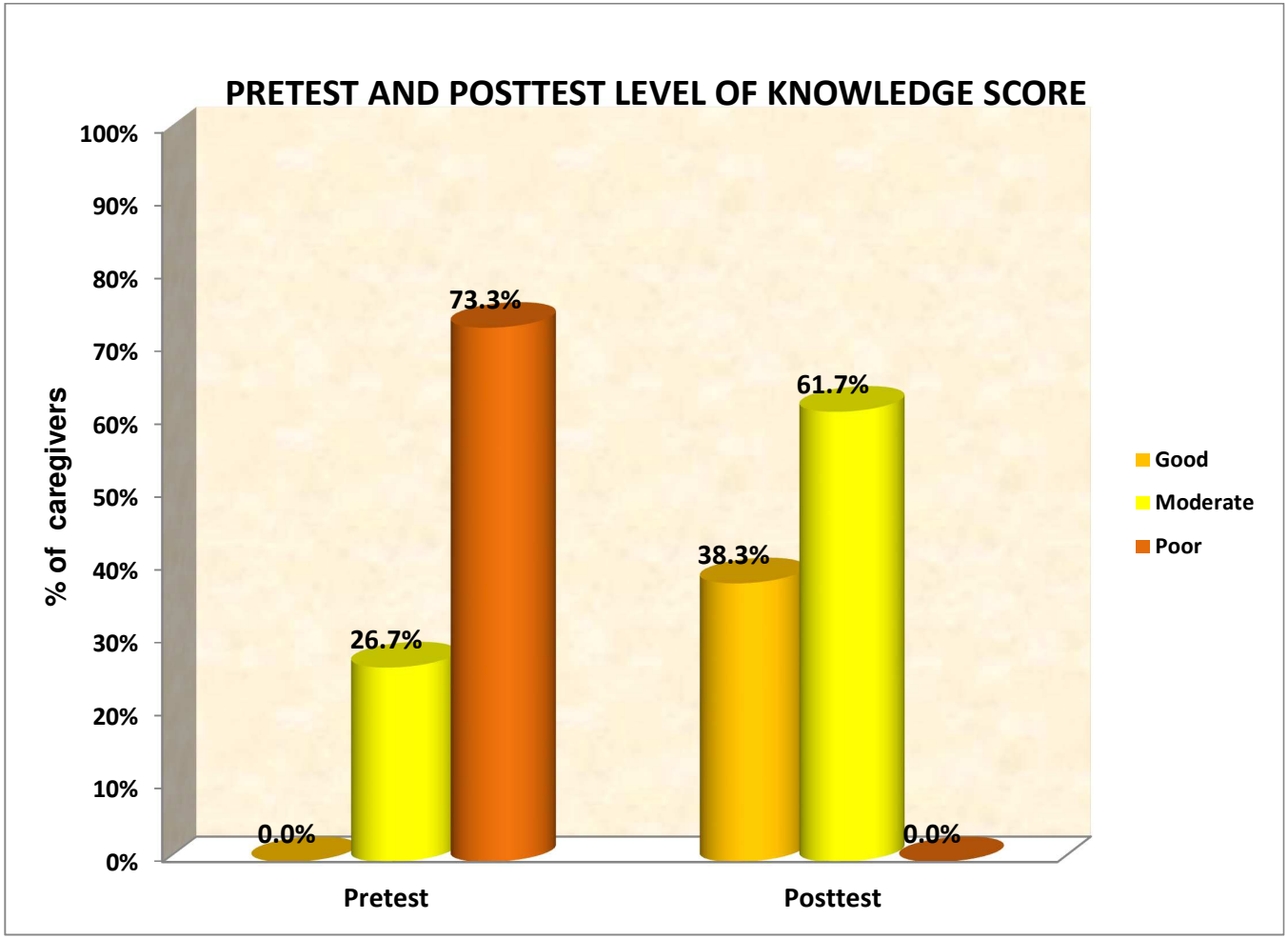


Fig 4.15. Pretest and posttest level of knowledge score among caregivers

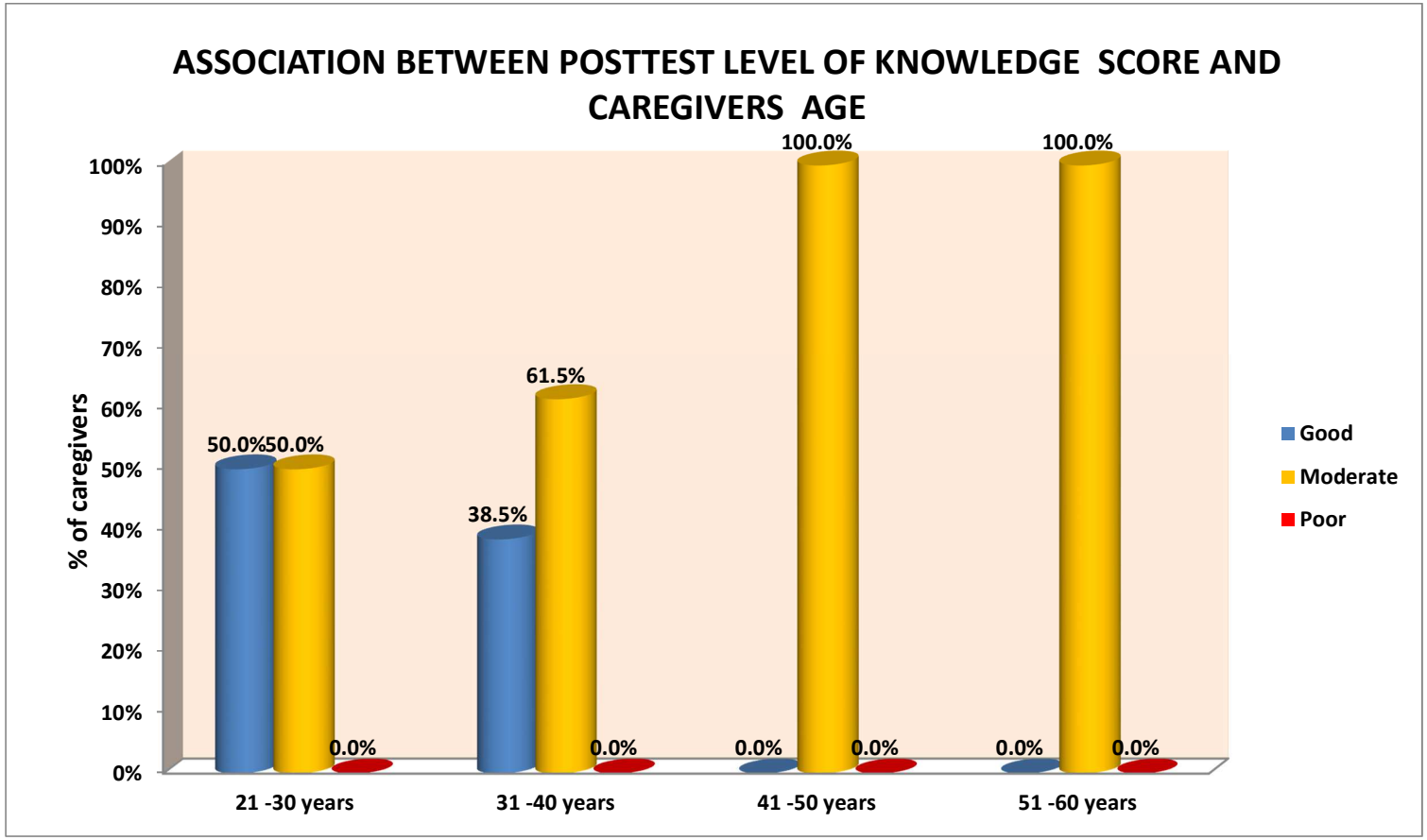


Fig 4.16 Association between posttest level of knowledge score and caregivers age

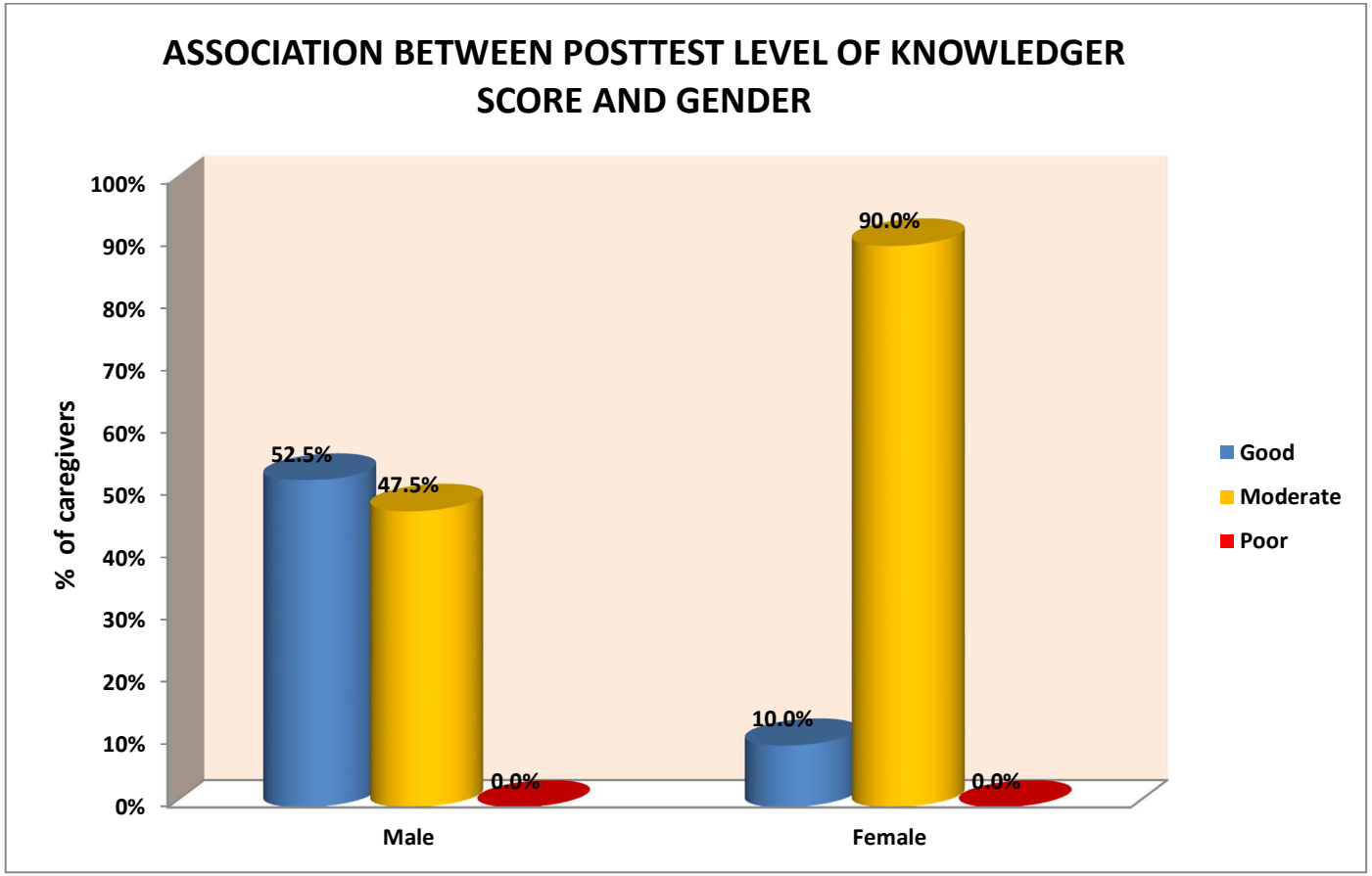


Fig 4.17. Association between posttest level of knowledge score and gender

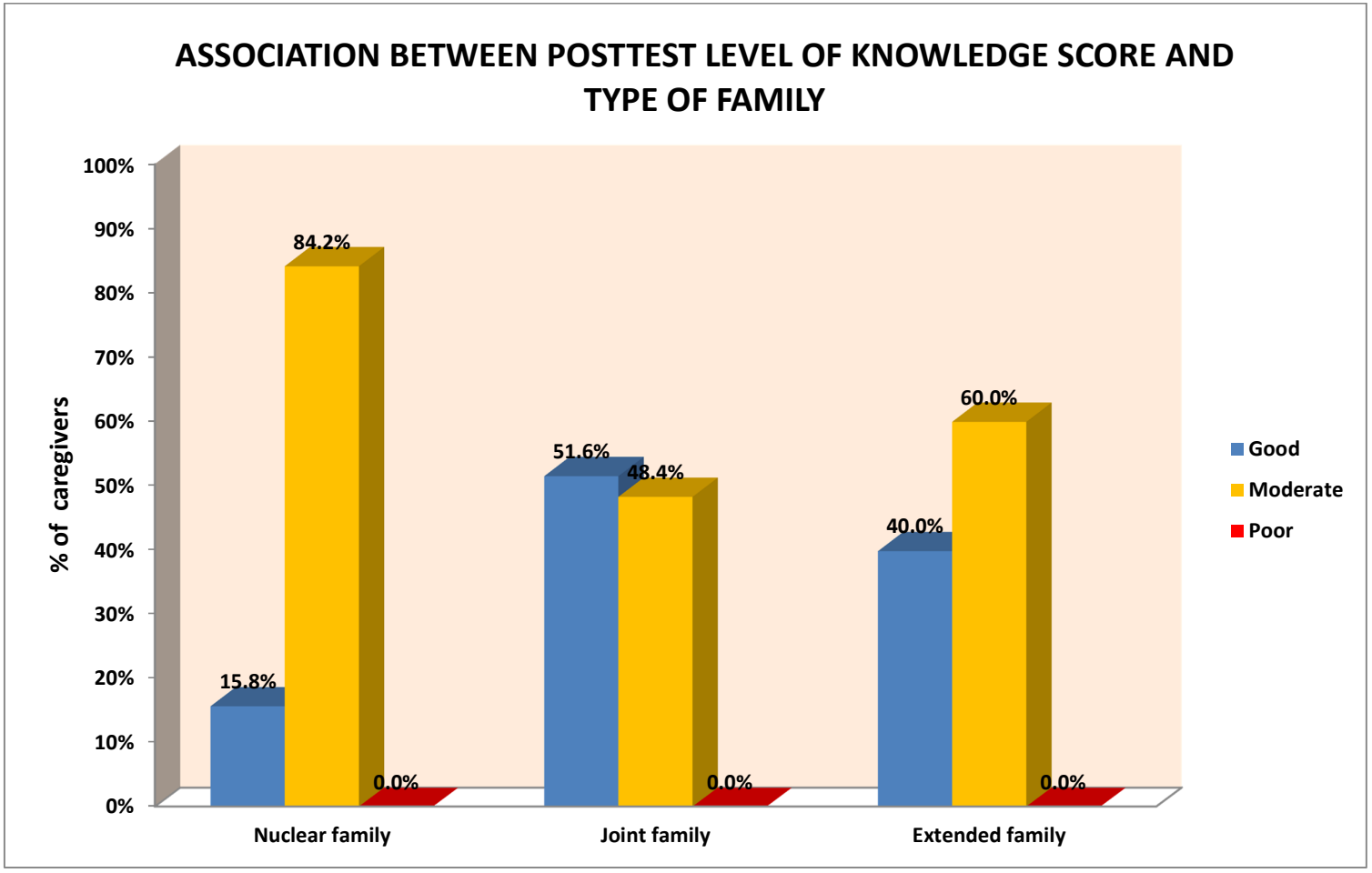


Fig 4.18 Association between posttest level of knowledge score and type of family

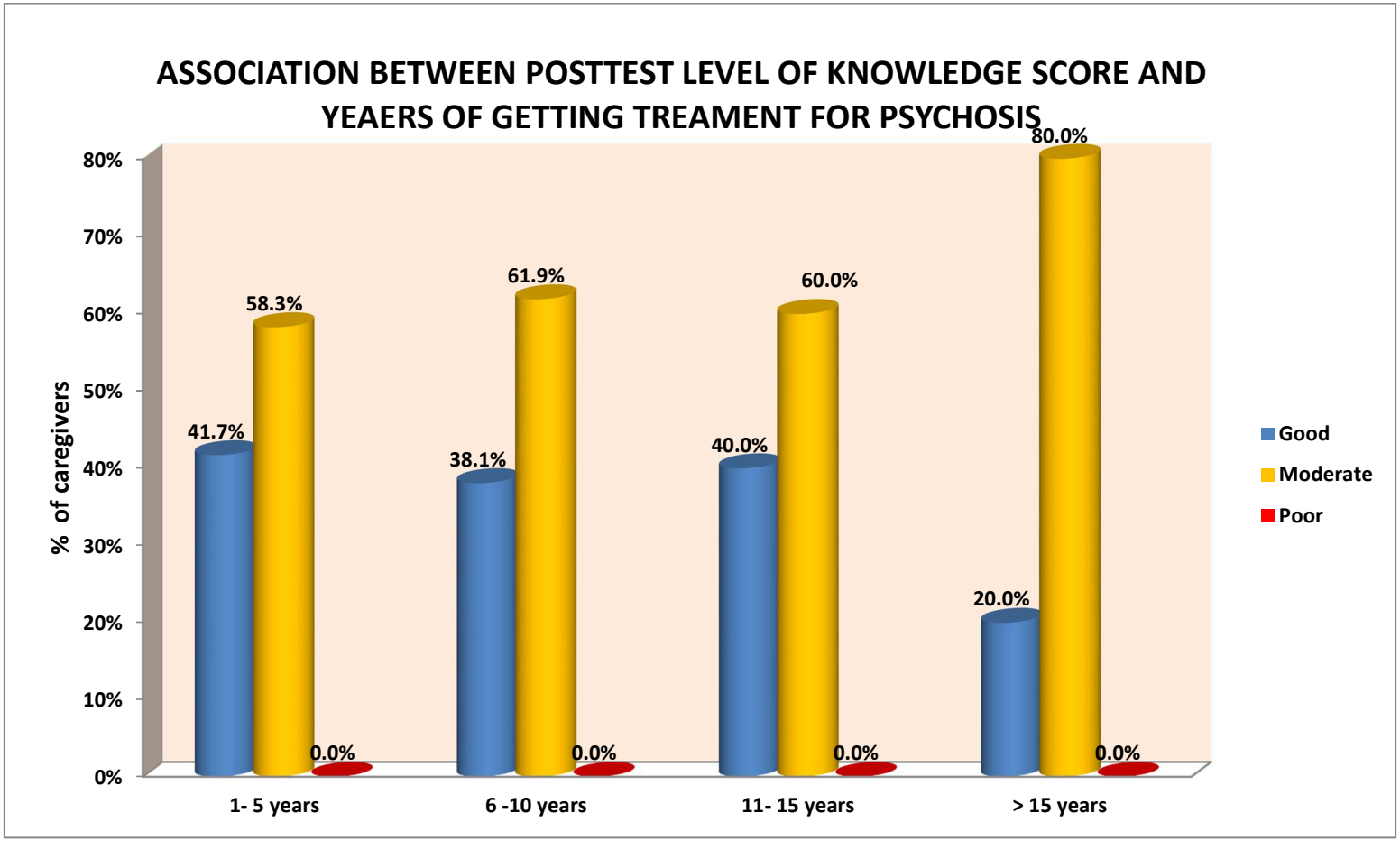


Fig 4.19. Association between post test level of knowledge score and years of getting treatment for psychosis

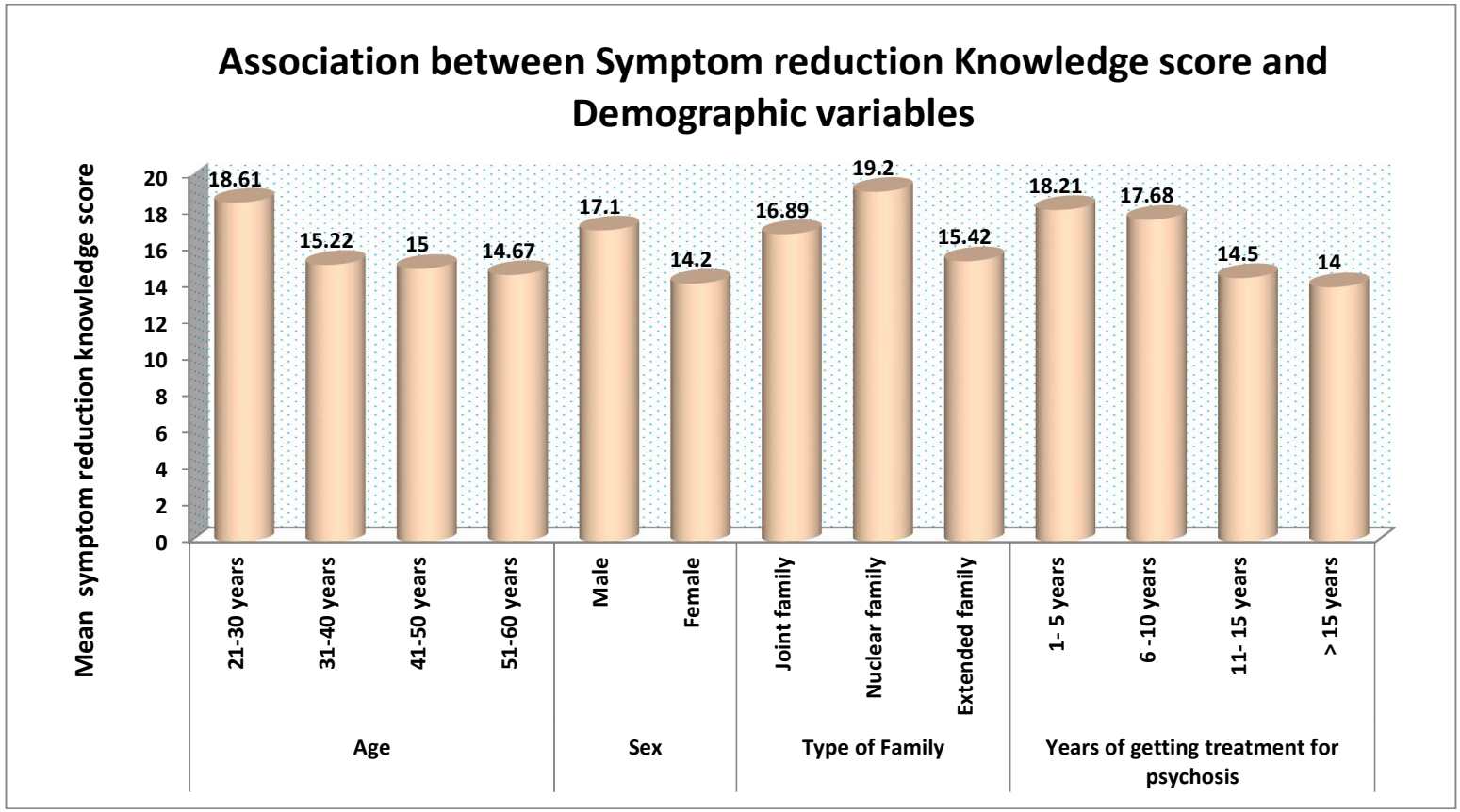


Fig 4.20 Association between symptom reduction knowledge score and demographic variables

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"A STUDY TO ASSESS THE EFFECTIVENESS OF PSYCHO EDUCATION MODULE ON KNOWLEDGE REGARDING EXTRA PYRAMIDAL SYMPTOMS AMONG CAREGIVERS OF PATIENTS ON ANTIPSYCHOTIC DRUGS ATTENDING OUTPATIENT DEPARTMENT AT IMH, CHENNAI"

PART – A -- SOCIO DEMOGRAPHIC VARIABLES

SOCIO DEMOGRAPHIC VARIABLES

1. Age ☐

a) 21 – 30 yrs
b) 31 – 40 yrs
c) 41 – 50 yrs
d) 51 – 60 yrs

2. Sex

a) Male
b) Female

3. Living area

a) Rural
b) Urban
c) Semi urban

4. Marriage

a) Married
b) Unmarried
c) Widow
d) Others

5. Occupation

a) Cooly
b) Business
c) State government.
d) Central government.

5. Family

a) Joint family

b) Nuclear family

c) Extended

6. Income of the family

a) Rs 5001- 10,000.

b) Rs 10,001- 20,000.

c) Rs 20,001- 30,000.

d) Rs 30,000 above

7. Years of getting treatmentfor psychosis

a) 1- 5 years

b) 6 -10 years

c) 11- 15 years

d) More than 15 years

PART-II

KNOWLEDGE PROFOMA

8. Side effects of antipsychotics are

a) Drawling of saliva.

b) Rigidity of body and neck.

c) Eye balls moves up.

d) Fever with palpitation.

9. EPS means

a) Extra psychiatric symptoms.

b) Extra pyramidal symptoms.

c) Extra pyramidal syndrome.

d) Extra six symptoms.

10. Treatment measure for EPS is

a) Getting treatment in psychiatric OPD.

b) Getting local traditional treatment.

c) Getting black magic treatment

d) Stop to attending psychiatric OPD.

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1. À¡Ä¦Éõ.

a) ¬ ñ

b) ¦À ñ

2. ÅÂÐ.

a) 21 –30 ÅÂÐ

b) 31 – 40 ÅÂÐ

c) 41 – 50ÅÂÐ

d) 51- 60 ÅÂÐ

3. Å¡ØÁ¦¼õ.

a) ¸¦Ã¡Áõ

b) ¿¸Ãõ

c) ¿¸Ãõ º¡÷ó¾

4.¾¦ÕÁ½ Å¦ÅÃõ.

a) ¾¦ÕÁ½Á¡É Å÷

b) ¾¦ÕÁ½Á¡¸òÅ÷

c) Å¦¾¨Å

e) ÁüüÅ÷

5. À½¦ Å¦ÅÃõ

a) Ü Ä¦

b) Å¦Â¡À¡Ãõ

c) «ÃÍ À½¦

d) Áò¾¦Â«ÃÍ À½¦

6. Ì Îõ À Å¦ÅÃõ

a) ¾É¦ Ì Îõ Àõ

b) Ü ð Î Ì Îõ Àõ

c) À¡Ãõ À¡¦Â Ì Îõ Àõ

7. Á¡¾ ÅÕÁ¡ Éõ

a) Rs.5000 -10000

b) Rs.10001-20000

c) Rs.20001 – 30000

d) Rs.30001 ì Ì §Áø

8. ÁÉº¢¨¾× §¿¡öì Ì º¢¸¢î¨º Ó¨È

a) 1 -5 ÅÕ¼õ

b) 6 -10 ÅÕ¼õ

c) 11 -15 ÅÕ¼õ

d) 15 ÅÕ¼í ¸ Ù ì Ì §Áø

À Ì ¾¢ - ¬ - §¿¡ö Ì È¢ò¾ Å¢ÅÃí ¸û

9. ÁÉº¢¨¾× ÁÕóÐ ¸Ç¡ø À¢ý Å¢¨Ç× ¸û

a) Å¡Â¢ø þÕóÐ ±î º¢ø ´Ø Ì ¾ø

b) Å¢¨ÃôÀ¡É ¸ØòÐ ÁüÚõ ¯¼ø

c) ¸ ñ ½¢ø À¡¨Å §Á§Ä þÕò¾ø

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10. ÁÉº¢¨¾× ÁÕóÐ ¸Ç¡ø À¢ý Å¢¨Ç× ¸û (E P S)

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b) ÁÕó¾¡ø À¢ý Å¢¨Ç×

c) À¢ý Å¢¨Ç× «È¢ Ì È¢ ¸û

d) À¢ý Å¢¨Ç× ¸û

11. ÁÉº¢¨¾× ÁÕóÐ ¸Ç¡ø À¢ý Å¢¨Ç× ¸û º¢¸¢î¨º Ó¨È

a) ÒÈ §¿¡ÂÇ÷ º¢¸¢î¨º À¢¡×

b) Å¢ðÊü Ì «Õ ¸¢ø º¢¸¢î¨º

c) Á¡Â Áó¾ÃõÃõ

d) ÒÈ §¿¡ÂÇ÷ º¢¸¢î¨º ì Ì

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Àł½łÂ¡Ç÷ ¿¡û

Å¡ØÁł¼õ ÅÂÐ À¡ÄłÉõ

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5	«Åý / «Åû ¾¨º þÕì¸Á¡¸ þÕò¾ø				
6	«Åý / «Åû ¨¸/¸¡ø ¬ ÎÅÐ ÐÊôÀ¾¡¸ ¯ûÇÐ				
7	«Åý / «Åû º¡łÅÃ ¿¼ì¸ ÓÊÂ¡Áø ¾ûÇ¡Ê þÕò¾ø				
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9	«Åý / «Åû ¿¼ôÀÐ ±ýÀÐ þÂø¨ÀÅ¼ Ì¨ÈÅ¡¸§Å ¯ûÇÐ				
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11	«Åý / «ÅûÀ¡÷¨Å ÁÍ¸Ä¡¸ ¯ûÇÐ				
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6	µôÀó¾õ - ¾ü¦¸¡ ¨ Äì Ì ¿¡¼¡Áø þÕò¾ø			
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A new self-rating scale for detecting atypical or second-generation antipsychotic side effects

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A new self-rating scale for detecting atypical or second-generation antipsychotic side effects

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Abstract

We aimed to construct and assess a new self rating scale to detect the side effects of second generation antipsychotics. This scale was designed to allow a timely, sensitive and reliable method of gathering information on the number and severity of side effects an individual suffers from. The Glasgow Antipscyhotic Side-effect Scale (GASS) was developed after literature review, discussion with members of the mental health team and with service user feedback. Fifty indivudals taking second generation antipsychotics completed the GASS along with the Liverpool Univeristy Neuroleptic Side Effect Rating Scale, and one week later completed the GASS for a second time. Fifty comparison subjects also completed the GASS. The GASS was shown to have good discrimatory power and construct validity, along with good re-test reliablity, and is put forward as a short, helpful and valid clinical tool.

Key words

neuroleptic drugs; atypical antipsychotics; antipsychotic agents/adverse effects; drug monitoring; questionnaires

Introduction

Adherence with antipsychotic medication is perhaps the main determinant of relapse in schizophrenia (Robinson, *et al*., 2002). The tolerability or experience of side effects of a particular antipsychotic medication has been regarded as both one of the key factors predicting continued adherence (Tacchi and Scott, 2005; Lambert, *et al*., 2004) and crucially the experience of adverse antipsychotic side effects is commonly stated by patients as an important reason for non-adherence (Patel and David, 2007). This highlights the importance of an open and systematic discussion regarding medication-related side effects, as an acknowledgement of the risks as well as benefits of a particular treatment help to establish a collaborative approach between clinicians and service users and contribute to a therapeutic rapport.

Antipsychotic side-effect rating scales have been used over the years to help identify and quantify the various side effects that can occur on these medications. A literature review was undertaken to identify all currently available antipsychotic side-effect rating scales using Medline and other Internet search engines with various keywords including *neuroleptic*, *side effects*, *antipsychotic*, *rating scale* and *schizophrenia*. Also, medical, pharmacy and nursing staff were questioned about their experience of identifying antipsychotic side effects. All nine currently widely available antipsychotic side-effect rating scales were identified and reviewed to identify their strengths and weaknesses (see Table 1).

Antipsychotic side effect rating scales have been around for a long time. They include traditional observer rated side-effect scales such as the Simpson-Angus (Simpson and Angus, 1970) or the Barnes Akathisia scale (Barnes, 1989). These more often were found in research settings than routine clinical practice, and arguably side-effect scales, focusing only on movement disorder or extra-pyramidal symptoms, have now become less relevant as the widely used atypical or second-generation antipsychotics (SGAs) have a lower incidence of extra-pyramidal side effects (Geddes, *et al*., 2000).

Additionally, although observer rated scales may avoid over-reporting bias, they can be more time consuming than self-report scales, and less likely to identify potentially embarrassing concerns such as sexual dysfunction. The Liverpool University Neuroleptic Side-Effect Rating Scale (LUNSERS) (Day, *et al*., 1995) is a commonly used self-report scale, which concentrates on one-word symptoms but again is over a decade old. The LUNSERS also takes time to complete as it is three pages long, and a recent audit (Negi, 2007) found that use of the LUNSERS did not improve case-record documentation of side effects. Finally, experience with the LUNSERS found that patients commonly have to ask for help in understanding terms

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such as 'chilblains', emphasising that the use of simple plain English is vital in self-report scales.

We aimed to devise an easy to understand self-report side-effect scale that was brief, valid, practical and informative. It was envisaged that a short self-report scale would facilitate further discussion in the clinic regarding the tolerability of antipsychotic medication.

Method

Ethical approval for the study was granted by the local Research and Ethics Committee.

Constructing the scale

After referring to existing scales, important antipsychotic side effects were listed using information from the British National Formulary (BNF 51, Joint Formulary Committee, 2005) and the pharmaceutical industry. Consistent with the NICE guidelines (NICE, 2002), these side effects were then ranked in importance by both authors in terms of medical consequences. In addition, a focus group of patients already taking antipsychotic medication ranked the list of side effects in terms of acceptability. Twenty-two questions were arrived at, which summarised the prioritised side effects with priority given to long-term adverse medical consequences. These were then grouped into medical systems (see Table 2).

The majority of side effects addressed by the new scale are contained in LUNSERS, but the 22 questions were converted into unambiguous plain English, The new scale, termed the Glasgow Antipsychotic Side-effect Scale or GASS was scored 0,1,2,3 for questions 1–20, with higher scores reflecting more frequent experience of side effects. Questions 21 and 22 scored 0 for 'no' and 3 for 'yes'. Total GASS scores were arbitrarily divided into suggested ranges for categorical severity, that is, 0–21 = absent/mild side effects; 22–42 = moderate side effects and 43–63 = severe side effects. A separate (unscored) column was added to allow people completing the GASS to note if the side effect experienced was distressing.

Participants

Fifty outpatients aged 18–65 who were currently prescribed and taking a SGA (regardless of diagnosis or other medication prescribed) consented to participate. These individuals were recruited from outpatient and clozapine clinics in the three North Glasgow resource centres. Adherence with prescribed medication was confirmed at interview. Fifty comparison subjects within the same age range also agreed to participate after excluding individuals on prescribed medication and those working in mental health care. These individuals were recruited by

Table 1 Existing side-effect rating scales

Scale	Number questions	Completion	Advantages	Disadvantages
Simpson Angus Scale (SAS) (Simpson and Angus, 1970)	10	Clinician rated	Objective rating of EPSE, quick and easy to perform	Focus on extrapyramidal side effects (EPSE) only
Abnormal Involuntary Movement Scale (AIMS)(Guy, 1976)	12	Clinician rated	Objectively records presence and severity of involuntary movements; quick to perform	Focus on abnormal movements only
Extrapyramidal Side Effect Rating Scale (ESRS) (Chouinard, *et al.*, 1980)	12	Clinician rated	Quick to perform, objective documenting of EPSE	EPSE only. No differentiation between dyskinesia and dystonia
Drug Attitude Inventory (Hogan, *et al.*, 1983)	30	Self rated	Simple to understand questions and true/false answers. Assesses attitude	Not specifically aimed at detecting antipsychotic side-effects
Side Effects Rating Scale for the Registration of Unwanted Effects of Psychotropics (Lingjaerde, *et al.*, 1987)	47	Clinician rated	Covers an extensive range of side effects from antipsychotic medication	Requires a lengthy semi structured interview and clinical observation
Barnes Akathisia Rating Scale (Barnes, 1989)	4	Clinician and self rated components	Both subjective and objective rating of akathisia; quick	Focuses on akathisia only
Hillside Akathisia Scale (HAS) (Fleischhaker, *et al.*, 1989)	5	Clinician and self rated components	Both subjective and objective rating of akathisia; quick	Focuses on akathisia only
Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) (Day, *et al.*, 1995)	51	Self rated	Assesses wide range of side effects; red herring questions for over-reporting of side-effects	One-word symptoms that can be difficult to understand
Antipsychotic Non-Neurological Side Effect Rating Scale (ANNSERS) (Yusufi, *et al.*, 2005)	35	Clinician and self rated components	Covers wide range of side effects for 1st and 2nd generation antipsychotics	Lengthy and time consuming

Table 2 Glasgow Antipsychotic Side-effect Scale (GASS)

Glasgow Antipsychotic Side-effect Scale (GASS)

Name: **Age:** **Sex: M / F**

Please list current medication and total daily doses below:

This questionnaire is about how you have been recently. It is being used to determine if you are suffering from excessive side effects from your antipsychotic medication.
Please place a tick in the column which best indicates the degree to which you have experienced the following side effects. Tick the **end** box if you found that the side effect distressed you.

*Over the **past week**:*	*Never*	*Once*	*A few times*	*Everyday*	*Tick this box if distressing*
1. I felt sleepy during the day					
2. I felt drugged or like a zombie					
3. I felt dizzy when I stood up and/or have fainted					
4. I have felt my heart beating irregularly or unusually fast					
5. My muscles have been tense or jerky					
6. My hands or arms have been shaky					
7. My legs have felt restless and/or I couldn't sit still					
8. I have been drooling					
9. My movements or walking have been slower than usual					
10. I have had, or people have noticed uncontrollable movements of my face or body					
11. My vision has been blurry					
12. My mouth has been dry					
13. I have had difficulty passing urine					
14. I have felt like I am going to be sick or have vomited					
15. I have wet the bed					
16. I have been very thirsty and/or passing urine frequently					
17. The areas around my nipples have been sore and swollen					
18. I have noticed fluid coming from my nipples					
19. I have had problems enjoying sex					
20. Men only: I have had problems getting an erection					

Tick yes or no for the following questions about the **last three months**	*No*	*Yes*	*Tick this box if distressing*
21. Women only: I have noticed a change in my periods			
22. Men and women: I have been gaining weight			

Staff Information

1. Allow the patient to fill in the questionnaire themselves. Questions 1-20 relate to the previous week and questions 21-22 to the last three months.

2. Scoring

   For questions 1-20 award 1 point for the answer "once", 2 points for the answer "a few times" and 3 points for the answer "everyday".
   Please note zero points are awarded for an answer of "never".

   For questions 21 and 22 award 3 points for a "yes" answer and 0 points for a "no".

   Total for all questions=

3. For male and female patients a *total score* of:
   0-21 = absent/mild side effects
   22-42 = moderate side effects
   43 and over = severe side effects

4. Side effects covered by questions *1-2* sedation and CNS side effects
   3-4 cardiovascular side effects
   5-10 extra-pyramidal side effects
   11-13 anticholinergic side effects
   14 gastro-intestinal side effects
   15 genitourinary side effects
   16 screening for diabetes mellitus
   17-21 prolactinaemic side effects
   22 weight gain

The column relating to the distress experienced with a particular side effect is not scored, but is intended to inform the clinician of the service user's views and condition.

directly approaching members of public in the streets of central Glasgow. Individuals unable to read English were also excluded.

Assessment of the new scale

Outpatients completed both the LUNSERS and the GASS at the same time, with the choice of which scale was completed first being randomly assigned via coin tossing. The outpatients were also asked to complete a copy of the GASS again a week later to assess test–retest reliability. Comparison subjects completed the GASS to report that the GASS could differentiate between those taking and those not taking SGAs.

Statistical analyses were performed using MedCalc for Windows, version 9.2.0.1 (*MedCalc Software*). Categorical

differences were determined using the Mann–Whitney test, with significance set at $P < 0.05$. Level of agreement between the scales was assessed using the weighted κ and Spearman correlation coefficient.

Results

The GASS is illustrated above (see Table 2).

Table 3 shows the mean ages and the mean GASS score for the two groups.

There was no significant difference in age between the two groups ($U = 1410$, $P = 0.27$). The GASS scores for the two groups differed significantly (Mann–Whitney *U*-test, $U = 2336$, $P < 0.0001$) with a mean of 14.3 for those on antipsychotic medication, and 3.6 for those not on medication. This confirms the construct validity of the GASS.

Figure 1 shows the spread of the GASS scores within each of the proposed categorical cut-off points, for both cases and normal comparisons. Cases prescribed polypharmacy or monotherapy are also shown separately. As expected, all controls scored within the absent to mild category.

Twenty-nine of the outpatient group were prescribed clozapine, nine risperidone (seven oral, two depot), eight olanzapine and four amisulpride. All doses were prescribed within BNF limits. Thirty-six outpatients were prescribed only a SGAs, whereas the remaining 14 were on other regular medications (eight on antidepressants, five on mood stabilisers, one procyclidine, one methadone and one oral hypoglycaemics).

Repeating the analysis of GASS scores excluding the results of the 14 polypharmacy outpatients still showed that outpatients had a significantly higher mean GASS score of 11.5 (SD = 7.9) and they differed significantly from the normal comparisons (*U* score 1681, $P < 0.0001$).

When the GASS was compared to the LUNSERS in the 50 outpatients, the κ score = 0.73, with Spearman rank correlation coefficient = 0.93 (sum of squared differences = 1548). This indicates a strong level of agreement between the GASS and LUNSERS.

Only 17 of the 50 outpatients returned (by post) the second GASS questionnaire adequately filled out a week later. Test–retest reliability was good, with κ = 0.72. The Mann–Whitney *U*-test failed to identify any significant difference in the GASS score of those who returned the second GASS questionnaire and those who did not ($U = 308$, $P = 0.57$) or in their age ($U = 284$, $P = 0.94$). There were 10 men and seven women in the group that returned the second GASS compared with 16 men and 17 women in the group that did not.

Table 3 Mean ages and GASS scores of participants

Statistic	Cases ($n = 50$)	Comparisons ($n = 50$)
Mean age (years) [SD]	41.4 [9.1]	39.9 [14.1]
Age range (years)	24–65	19–65
No. males	26	21
Mean GASS [SD]	14.3 [10.5]	3.6 [4.1]

GASS, Glasgow Antipsychotic Side-effect Scale; SD, standard deviation.

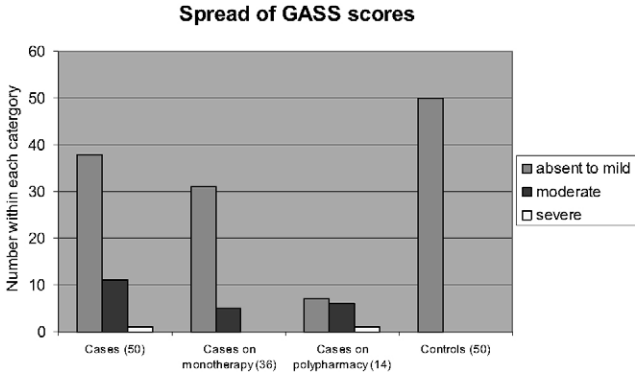

Figure 1 Spread of Glasgow Antipsychotic Side-effect Scale scores.

Discussion

We have constructed a new self-report rating scale assessing SGA side effects that is easy to use. The GASS takes 5 min to complete and contains self-explanatory questions in everyday plain English while providing a structured systematic method of reviewing antipsychotic side effects. In the waiting room of a busy community mental health team or on the inpatient unit, the use of simple and jargon-free language will surely enhance understanding and accurate completion of a self-report scale, particularly if that scale is seen as brief. Furthermore, recognising that the experience of a side effect may not necessarily be adverse even if it is common or may not cause distress or functional impairment when present, following our data collection we added a column to the GASS allowing the subject to rate whether the experienced side effect was in fact distressing (or not). This was left as a simple global 'yes/no' response in view of the complexity of this judgement. Thus, the GASS allows a grading not only of the frequency of an experienced side effect but also a subjective judgement of the distress associated with a particular side effect.

The widespread use of SGAs along with their recommendation by influential guidelines (NICE, 2002) is in large part because of a perception of increased tolerability, although recent independent studies (e.g., Lieberman, *et al*., 2005) have confirmed SGAs have important adverse side effects with associated long-term health implications. Many studies have reported that adherence with prescribed medication is a key determinant of relapse prevention (seeTacchi and Scott, 2005), and medication side effects are commonly cited by patients as a main reason for non-adherence (Patel and David, 2007), perhaps because clinicians consistently underestimate the severity and frequency of side effects. The routine use of rating scales or systematised evaluation in psychiatry is not

widespread, but arguably will increase and can be used to enhance the clinician–patient interaction. Self-report scales generally are less onerous for the busy clinician but also allow more complete and considered responses as well as minimising potential embarrassment on subjects such as sexual dysfunction.

Older side-effect rating scales (see Table 1) such as AIMS, Simpson Angus and Barnes Akathisia tended to focus exclusively on movement disorder and extrapyramidal symptoms and were usually observer rated. The more recent scales such as LUNSERS and ANNSERS are more comprehensive and suitable for SGAs but are lengthy and time consuming. The LUNSERS is regularly used in the United Kingdom, despite its size, age and occasionally confusing language, illustrating that a systematic appraisal of medication side effects is considered important. Both the weighted κ score and Spearman's rank correlation score reported a very good level of agreement between the LUNSERS and the GASS in a representative psychiatric outpatient population. This is not surprising given that the majority of the questions in the GASS are also covered by the LUNSERS. The test–retest results also indicate that the GASS is reliable and stable over time. We reported that individuals taking SGAs had significantly higher GASS scores than matched normal comparison subjects, as hypothesised, and this was not confounded by polypharmacy.

We believe our use of medical and consumer opinion as well as the literature review enhances the face validity of the GASS, and as the GASS combines brevity with validity, it is suitable for busy clinical environments and as part of routine clinical monitoring, for example, during ward round or outpatient review. The GASS can also be completed outside the actual clinical interview, and can thus open up discussion between clinician and service user on medication tolerability in a systematic and structured manner, rather than relying on an *ad hoc* approach.

Given these results, we suggest the GASS is a valid reliable tool, which could aid systematic clinical assessment, particularly in view of its brevity and user-friendly language.

Study limitations

The GASS was only assessed in outpatients taking SGAs; hence, the results may not be applicable to those on typical or first-generation antipsychotics or acute inpatients. It may not be possible to generalise the results of this study beyond a white middle-aged population in view of the age range and ethnicity of the two study groups. The subjective rating of distress caused by each side effect requires further study.

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